P7_TA(2014)0267

In vitro diagnostic medical devices ***I

European Parliament legislative resolution of 2 April 2014 on the proposal for a regulation of the European Parliament and of the Council on in vitro diagnostic medical devices (COM(2012)0541 – C7-0317/2012 – 2012/0267(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2012)0541),

– having regard to Article 294(2) and Articles 114 and Article 168(4)(c) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0317/2012),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the opinion of the European Economic and Social Committee of 14 February 2013[1],

– after consulting the Committee of the Regions,

– having regard to Rule 55 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Employment and Social Affairs and the Committee on the Internal Market and Consumer Protection (A7-0327/2013),

1. Adopts as its position at first reading the text adopted on 22 October 2013[2];

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

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1 OJ C 133, 9.5.2013, p. 52.
2 P7_TA(2013)0427.

P7_TC1-COD(2012)0267

Position of the European Parliament adopted at first reading on 2 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on in vitro diagnostic medical devices

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4)(c) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

After consulting the Committee of the Regions,

After consulting the European Data Protection Supervisor[2],

Acting in accordance with the ordinary legislative procedure[3],

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1 OJ C 133, 9.5.2013, p. 52.
2 OJ C 358, 7.12.2013, p. 10.
3 Position of the European Parliament of 2 April 2014.

Whereas:

(1) Directive 98/79/EC of the European Parliament and of the Council[1] constitutes the Union regulatory framework for *in vitro* diagnostic medical devices. However, a fundamental revision of that Directive is needed to establish a robust, transparent, predictable and sustainable regulatory framework for devices which ensures a high level of safety and health whilst supporting innovation.

(2) This Regulation aims to ensure the functioning of the internal market as regards in vitro diagnostic medical devices, taking as a base a high level of protection of health ***for patients, users and operators***. At the same time, this Regulation sets high standards of quality and safety for devices to meet common safety concerns as regards those products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 of the Treaty on the Functioning of the European Union ***(TFEU)***, this Regulation harmonises the rules for the placing on the market and putting into service of in vitro diagnostic medical devices and their accessories on the Union market which may then benefit from the principle of free movement of goods. As regards Article 168(4)(c) ~~of the Treaty on the Functioning of the European Union~~***TFEU***, this Regulation sets high standards of quality and safety for those devices by ensuring, among other things, that data generated in clinical performance studies is reliable and robust and that the safety of subjects participating in clinical performance studies is protected.
[Am. 1]

[1] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices[1] constitutes the Union regulatory framework for *in vitro* (OJ L 331, 7.12.1998, p. 1).

(3) Key elements of the existing regulatory approach, such as the supervision of notified bodies, ~~risk classification~~, conformity assessment procedures, clinical ~~evidence~~ ***investigations and clinical evaluation***, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding *in vitro* diagnostic medical devices should be introduced to improve health and safety ***for health professionals, patients, users and operators, including in the waste disposal chain***. **[Am. 2]**

(4) To the extent possible, guidance developed for *in vitro* diagnostic medical devices at international level, in particular in the context of the Global Harmonization Task Force (GHTF) and its follow-up initiative the International Medical Devices Regulators Forum, should be taken into account to promote the global convergence of regulations which contributes to a high level of safety worldwide and to facilitate trade, in particular in the provisions on Unique Device Identification, general safety and performance requirements, technical documentation, classification criteria, conformity assessment procedures and clinical evidence.

(5) There are specific features of *in vitro* diagnostic medical devices, in particular in terms of risk classification, conformity assessment procedures and clinical evidence, and of the *in vitro* diagnostic medical device sector which require the adoption of a specific legislation, distinct from the legislation on other medical devices, whereas the horizontal aspects common to both sectors should be aligned ***without compromising the need for innovation in the Union***. **[Am. 3]**

(5a) The high number of small and medium enterprises (SMEs) active in the area of in-vitro diagnostic medical devices should be taken into account when regulating that area, while avoiding the creation of health and safety risks. **[Am. 4]**

(6) A Regulation is the appropriate legal instrument as it imposes clear and detailed rules which do not give room for divergent transposition by Member States. Moreover, a Regulation ensures that legal requirements are implemented at the same time throughout the Union.

(7) The scope of application of this Regulation should be clearly delimited from other legislation concerning products such as medical devices, general laboratory products and products for research use only.

(7a) ***A multidisciplinary Medical Device Advisory Committee (MDAC) composed of experts and representatives of the relevant stakeholders should be set up to provide scientific advice to the Commission, the Medical Device Coordination Group (MDCG) and Member States on issues of medical technology, the regulatory status of devices and other aspects of implementation of this Regulation as necessary.*** **[Am. 5]**

(8) ~~It~~ ***In order to ensure consistent classification across all Member States, particularly with regard to borderline cases, it*** should be the responsibility of the ~~Member States~~ ***Commission, having consulted the MDCG and the MDAC,*** to decide on a case-by-case basis whether or not a product ~~falls~~ ***or groups of products fall*** within the scope of this Regulation. ~~If necessary, the Commission may decide, on a case-by-case basis, whether or not a product falls within the definition of an *in vitro* diagnostic medical device or of an accessory to an *in vitro* diagnostic medical device.~~ ***Member States should also have the possibility to request the Commission to take a decision on the appropriate regulatory status of a product, or category or group of products.*** **[Am. 6]**

(9) To ensure the highest level of health protection, the rules governing *in vitro* diagnostic medical devices manufactured and used, including measurement and delivery of results, only within a single health institution should be clarified and strengthened.

(9a) In the case of urgent or unmet medical needs for patients, such as emerging pathogens and rare diseases, single health institutions should have the possibility of manufacturing, modifying and using devices in-house and thereby addressing, within a non-commercial and flexible framework, specific needs which cannot be met by an available CE-marked device. **[Am. 7]**

(9b) However, devices which are manufactured within non-health institution laboratories and put into service without being placed onto the market should be subject to this Regulation. **[Am. 8]**

(10) It should be clarified that software specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of an *in vitro* diagnostic medical device is qualified as an *in vitro* diagnostic medical device, while software for general purposes, even when used in a healthcare setting, or software intended for well-being applications is not qualified as an *in vitro* diagnostic medical device.

(11) It should be made clear that all tests that provide information on the predisposition to a medical condition or a disease (e.g. genetic tests) and tests that provide information to predict treatment response or reactions, such as companion diagnostics, are *in vitro* diagnostic medical devices.

(12) Aspects addressed by Directive 2004/108/EC of the European Parliament and of the Council [1] and aspects addressed by Directive 2006/42/EC of the European Parliament and of the Council[2] are an integral part of the general safety and performance requirements for *in vitro* diagnostic medical devices. Consequently, this Regulation should be considered a *lex specialis* in relation to those Directives.

(13) This Regulation should include requirements regarding the design and manufacture of *in vitro* diagnostic medical devices emitting ionising radiation without affecting the application of Council Directive 96/29/Euratom[3], nor of Council Directive 97/43/Euratom[4] which pursue other objectives.

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1 Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC (OJ L 390, 31.12.2004, p. 24).

2 Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24).

3 Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (OJ L 159, 29.6.1996, p. 1).

4 Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure and repealing Directive 84/466/Euratom (OJ L 180, 9.7.1997, p. 22).

(13a) Directive 2013/35/EU of the European Parliament and of the Council[1] should be the reference text for ensuring that people working in the vicinity of magnetic resonance imaging equipment when it is in operation are properly protected. **[Am. 9]**

(14) It should be made clear that the requirements of this Regulation also apply to the countries that have entered into international agreements with the Union which confer on that country the same status as a Member State for the purpose of application of this Regulation, as it is currently the case with the Agreement on the European Economic Area[2], the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment[3] and the Agreement of 12 September 1963 establishing an association between the European Economic Community and Turkey[4].

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1 ***Directive 2013/35/EU of the European Parliament and of the Council of 26 June 2013 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (20th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) and repealing Directive 2004/40/EC (OJ L 179, 29.6.2013, p. 1).***

2 OJ L 1, 3.1.1994, p. 3.

3 OJ L 114, 30.4.2002, p. 369.

4 OJ 217, 29.12.1964, p. 3687.

(15) It should be made clear that *in vitro* diagnostic medical devices offered to persons in the Union by means of information society services within the meaning of Directive 98/34/EC of the European Parliament and of the Council[1] as well as devices used in the context of a commercial activity to provide a diagnostic or therapeutic service to persons within the Union must comply with the requirements of this Regulation at the latest when the product is placed on the market or the service is provided in the Union.

(16) To recognise the important role of standardisation in the field of *in vitro* diagnostic medical devices, compliance with harmonised standards as defined in Regulation (EU) No [Ref. of future Regulation on European standardisation] on European standardisation[2] should be a means for manufacturers to demonstrate conformity with the general safety and performance requirements and other legal requirements, such as quality and risk management.

(17) The definitions in the field of *in vitro* diagnostic medical devices, for example, regarding economic operators, clinical evidence and vigilance, should be aligned with well-established practice at Union and international level in order to enhance legal certainty.

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1 Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations (OJ L 204, 21.7.1998, p. 37), as amended by Directive 98/48/EC of the European Parliament and of the Council (OJ L 217, 5.8.1998, p. 18).

2 OJ L […], […], p. […].

(18) The rules applicable to *in vitro* diagnostic medical devices should be aligned, where appropriate, with the New Legislative Framework for the Marketing of Products, which consists of Regulation (EC) No 765/2008 of the European Parliament and of the Council[1] and Decision No 768/2008/EC of the European Parliament and of the Council[2].

(19) The rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to *in vitro* diagnostic medical devices and their accessories covered by this Regulation which does not prevent Member States from choosing the competent authorities to carry out those tasks.

(20) It is appropriate to set out clearly the general obligations of the different economic operators, including importers and distributors, as laid down in the New Legislative Framework for the Marketing of Products, without prejudice to the specific obligations laid down in the different parts of this Regulation, to enhance understanding of the legal requirements and thus to improve regulatory compliance by the relevant operators.

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1 Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

2 Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

(21) To ensure that *in vitro* diagnostic medical devices manufactured in series production continue to be in conformity with the requirements of this Regulation and that experience from the use of their *in vitro* diagnostic medical devices is taken into account for the production process, all manufacturers should have a quality management system and a post-market surveillance plan in place which should be proportionate to the risk class and the type of the *in vitro* diagnostic medical device.

(22) It should be ensured that supervision and control of the manufacture of *in vitro* diagnostic medical devices is carried out within the manufacturer's organisation by a person who fulfils minimum conditions of qualification. ***In addition to regulatory compliance, that person could also be responsible for compliance in other fields such as manufacturing processes and quality assessment. The required qualifications of the person responsible for the regulatory compliance should be without prejudice to national provisions regarding professional qualifications, in particular for manufacturers of custom-made devices where such requirements could be met through different educational and professional training systems at national level.*** **[Am. 10]**

(23) For manufacturers who are not established in the Union, the authorised representative plays a pivotal role in ensuring the compliance of the *in vitro* diagnostic medical devices produced by those manufacturers and in serving as their contact person established in the Union. The tasks of an authorised representative should be defined in a written mandate with the manufacturer which for example may allow the authorised representative to lodge an application for a conformity assessment procedure, to report events under the vigilance system or to register devices placed on the Union market. The mandate should empower the authorised representative to duly fulfil certain defined tasks. Considering the role of authorised representatives, the minimum requirements to be met by them should be clearly defined, including the requirement of having available a person who fulfils minimum conditions of qualification which should be similar to those for a manufacturer's qualified person but, with a view to the authorised representative's tasks, could also be satisfied by a person with qualification in law.

(24) To ensure legal certainty in respect of the obligations incumbent on economic operators, it is necessary to clarify when a distributor, importer or other person is to be considered the manufacturer of an *in vitro* diagnostic medical device.

(25) Parallel trade in products already placed on the market is a lawful form of trade within the internal market on the basis of Article 34 of the Treaty on the Functioning of the European Union subject to the limitations set by the protection of health and safety and by the protection of intellectual property rights provided by Article 36 of the Treaty on the Functioning of the European Union. Application of this principle is, however, subject to different interpretations in the Member States. The conditions, in particular the requirements for relabelling and repackaging, should therefore be specified in this Regulation, taking into account the case-law of the European Court of Justice[1] in other relevant sectors and existing good practices in the field of *in vitro* diagnostic medical devices.

(25a) To ensure that patients harmed are compensated for any damage and associated treatment as a result of a faulty in vitro diagnostic medical device, that the risk of damage as well as the risk of the manufacturer's insolvency are not shifted to patients harmed by a faulty in vitro diagnostic medical device, manufacturers should be obliged to take liability insurance with sufficient minimum coverage. **[Am. 11]**

1 Judgment of the Court of 28 July 2011 in joined cases C-400/09 and C-207/10.

(26) *In vitro* diagnostic medical devices should, as a general rule, bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the Union and be put into service in accordance with their intended purpose. Member States should not create obstacles to their placing on the market or putting into service for reasons related to the requirements laid down in this Regulation. ***However Member States should be allowed to decide whether to restrict the use of any specific type of in-vitro diagnostic device in relation to aspects that are not covered by this Regulation.*** **[Am. 12]**

(27) The traceability of *in vitro* diagnostic medical devices by means of a Unique Device Identification (UDI) system based on international guidance should significantly enhance the effectiveness of the post-market safety of *in vitro* diagnostic medical devices due to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against counterfeit devices. Use of the UDI system should also improve ~~purchase policy and stock management by hospitals~~ ***purchasing and waste disposal policies and hospitals', wholesalers' and pharmacists' management of stock and, where possible, be compatible with other authentication systems already in place in those settings***. **[Am. 13]**

(28) Transparency and ~~better~~ ***adequate access to*** information***, appropriately presented for the intended user,*** are essential to empower patients and healthcare professionals ***and all others concerned,*** and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system. **[Am. 14]**

(29) One key aspect is the creation of a central database that should integrate different electronic systems, with the UDI as an integral part of it, to collate and process information regarding *in vitro* diagnostic medical devices on the market and the relevant economic operators, certificates, interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies, vigilance and market surveillance. The objectives of the database are to enhance overall transparency, ***via better access to information for the public and healthcare professionals,*** to streamline and facilitate the flow of information between economic operators, notified bodies or sponsors and Member States as well as between Member States among themselves and with the Commission, to avoid multiple reporting requirements and to enhance the coordination between Member States. Within an internal market, this can be ensured effectively only at Union level and the Commission should therefore further develop and manage the European databank on medical devices (Eudamed) by further developing the databank set up by Commission Decision 2010/227/EU[1]. **[Am. 15]**

[1] Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices. (OJ L 102, 23.4.2010, p. 45).

(30) Eudamed's electronic systems ~~regarding devices on the market, the relevant economic operators and certificates~~ should enable the public ***and healthcare professionals*** to be adequately informed about devices on the Union market. ***Adequate levels of access for the public and healthcare professionals to those parts of Eudamed's electronic systems which provide key information on in vitro diagnostic medical devices that may pose a risk to public health and safety is essential. Where such access is limited, it should be possible, upon a reasoned request, to disclose the existing information on in vitro diagnostic medical devices, unless the limitation of access is justified on grounds of confidentiality.*** The electronic system on clinical performance studies should serve as tool for the cooperation between Member States and for enabling sponsors to submit, on a voluntary basis, a single application for several Member States and, in this case, to report serious adverse events. The electronic system on vigilance should enable manufacturers to report serious incidents and other reportable events and to support the coordination of their assessment by national competent authorities. The electronic system regarding market surveillance should be a tool for the exchange of information between competent authorities. ***A regular overview of vigilance and market surveillance information should be made available to healthcare professionals and the public.*** **[Am. 16]**

(31) In respect of data collated and processed through the electronic systems of Eudamed, Directive 95/46/EC of the European Parliament and of the Council[1] applies to the processing of personal data carried out in the Member States, under the supervision of the Member States competent authorities, in particular the public independent authorities designated by the Member States. Regulation (EC) No 45/2001 of the European Parliament and of the Council[2], applies to the processing of personal data carried out by the Commission within the framework of this Regulation, under the supervision of the European Data Protection Supervisor. In accordance with Article 2(d) of Regulation (EC) No 45/2001, the Commission should be designated as the controller of Eudamed and its electronic systems.

(32) For high-risk *in vitro* diagnostic medical devices, ***in the interests of increased transparency,*** manufacturers should ~~summarise the main~~ ***draw up a report on the*** safety and performance aspects of the device and the outcome of the clinical evaluation ~~in a document that~~***. A summary of the safety and performance report*** should be publicly available ***via Eudamed***. **[Am. 17]**

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1 Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

2 Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

(32a) ***According to the policy of the European Medicines Agency (EMA) on access to documents, the EMA releases documents submitted as part of applications for marketing authorisation for medicinal products, including clinical trial reports, on request once the decision-making process for the medicinal product in question has been completed. Corresponding standards on transparency and access to documents should be upheld and reinforced for high-risk in vitro diagnostic medical devices, in particular as they are not subject to pre-market approval. For the purposes of this Regulation, in general the data included in clinical performance studies should not be considered commercially sensitive provided that compliance of a device with the applicable requirements has been demonstrated following the applicable conformity assessment procedure. This should be without prejudice to intellectual property rights concerning the use by other manufacturers of data from clinical performance studies by the manufacturer.*** **[Am. 18]**

(33) The proper functioning of notified bodies is crucial for ensuring a high level of health and safety and citizens' confidence in the system. Designation and monitoring of notified bodies by the Member States, ***and where applicable by the EMA,*** in accordance with detailed and strict criteria, should therefore be subject to controls at Union level. **[Am. 19]**

(34) The position of notified bodies vis-à-vis manufacturers should be strengthened, including their right and duty to carry out unannounced factory inspections and to conduct physical or laboratory tests on *in vitro* diagnostic medical devices to ensure continuous compliance by manufacturers after receipt of the original certification.

~~(35) For high risk *in vitro* diagnostic medical devices, authorities should be informed at an early stage about devices which are subject to conformity assessment and be given the right, on scientifically valid grounds, to scrutinise the preliminary assessment conducted by notified bodies, in particular regarding devices for which no common technical specifications exist, devices which are novel or for which a novel technology is being used, devices belonging to a category of devices with increased serious incident rates, or devices for which significant discrepancies in the conformity assessments by different notified bodies have been identified in respect of substantially similar devices. The process foreseen in this Regulation does not prevent a manufacturer from informing voluntarily a competent authority of his intention to file an application for conformity assessment for a high risk *in vitro* diagnostic medical device before submitting the application to the notified body.~~ **[Am. 20]**

(36) To enhance patient safety and to take due account of technological progress, the risk classification system for *in vitro* diagnostic medical devices set out in Directive 98/79/EC should be fundamentally changed, in line with international practice, and the corresponding conformity assessment procedures should be accordingly adapted.

(37) It is necessary, in particular for the purpose of the conformity assessment procedures, to classify *in vitro* diagnostic medical devices into four risk classes and to establish a set of robust risk-based classification rules, in line with international practice.

(38) The conformity assessment procedure for class A *in vitro* diagnostic medical devices should be carried out, as a general rule, under the sole responsibility of the manufacturers, since such devices pose a low risk to patients. For *in vitro* diagnostic medical devices in classes B, C and D, the involvement of a notified body should be compulsory to the appropriate degree.

(39) The conformity assessment procedures should be further developed whilst the requirements for notified bodies as regards the performance of their assessments should be clearly specified to ensure a level playing field.

(40) It is necessary to clarify the requirements regarding batch release verification for the highest risk *in vitro* diagnostic medical devices.

(40a) Clinical expertise and specialist product knowledge within notified bodies, special notified bodies and the MDCG should be appropriate for the specifications of in vitro diagnostic medical devices. Clinical experts should have expertise in clinical interpretation of in vitro diagnostic results, metrology and good laboratory practice. Clinical experts and product specialists should have expertise in fields such as virology, haematology, clinical analysis and genetics. **[Am. 262]**

(41) European Union reference laboratories should be enabled to verify compliance of such devices with the applicable common technical specifications, when such common technical specifications are available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent.

(42) To ensure a high level of safety and performance, demonstration of compliance with the general safety and performance requirements should be based on clinical evidence. It is necessary to clarify the requirements for such clinical evidence. As a general rule, clinical evidence should be sourced from clinical performance studies to be carried out under the responsibility of a sponsor who can be the manufacturer or another legal or natural person taking responsibility for the clinical performance study.

(43) The rules on clinical performance studies should be in line with major international guidance, such as the international standard ISO 14155:2011 on good clinical practice for clinical investigations of medical devices for human subjects and the most recent (2008) version of the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects to ensure that clinical performance studies conducted in the Union are accepted elsewhere and that clinical performance studies conducted outside the Union in accordance with international guidelines can be accepted under this Regulation.

(43a) The Declaration of Helsinki of the World Medical Association[1] states in Article 23 that "The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins." Interventional clinical performance studies and other clinical performance studies involving risk for the subject should only be allowed after assessment and approval by an ethics committee. The reporting Member State and the other concerned Member States need to organise themselves in a way that the competent authority concerned receives approval from an ethics committee on the clinical performance study protocol. **[Am. 22]**

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1 ***WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and lastly amended by the 59th WMA General Assembly, Seoul, Korea, October 2008. http://www.wma.net/en/30publications/10policies/b3/index.html.pdf?print-media-type&footer-right=[page]/[toPage]***

(44) An electronic system should be set up at Union level to ensure that every interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies are registered in a publicly accessible database. To protect the right to protection of personal data, recognised by Article 8 of the Charter of Fundamental Rights of the European Union, no personal data of subjects participating in a clinical performance studies should be recorded in the electronic system. To ensure synergies with the area of clinical trials on medicinal products, the electronic system on clinical performance studies on *in vitro* diagnostic medical devices should be interoperable with the EU database to be set up for clinical trials on medicinal products for human use.

(44a) For the sake of transparency, sponsors should submit the results of a clinical performance study together with a 'layperson' summary within the deadlines specified by the regulation. The Commission should be empowered to adopt delegated acts on the preparation of the layperson's summary and the communication of the clinical performance study report. The Commission should provide guidelines for managing, and facilitating the sharing of, raw data from all clinical performance studies. **[Am. 23]**

(45) Sponsors of interventional clinical performance studies and other clinical performance studies involving risks for the subjects to be conducted in more than one Member State should be given the possibility to submit a single application in order to reduce administrative burden. In order to allow for resource-sharing and to ensure consistency regarding the assessment of the health and safety related aspects of the device for performance evaluation and of the scientific design of the clinical performance study to be conducted in several Member Stats, such single application should facilitate the coordination between the Member States under the direction of a coordinating Member State. ~~The coordinated assessment should not include the assessment of intrinsically national, local and ethical aspects of a clinical performance study, including informed consent.~~ Each Member State should retain the ultimate responsibility for deciding whether the clinical performance study may be conducted on its territory. **[Am. 24]**

(45a) Strict rules for persons unable to give informed consent such as children and incapacitated persons should be established at the same level as in Directive 2001/20/EC of the European Parliament and of the Council[1]. **[Am. 25]**

1 ***Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).***

(46) Sponsors should report certain adverse events occurring during interventional clinical performance studies and other clinical performance studies involving risks for the subjects to the Member States concerned which should have the possibility to terminate or suspend these studies if considered necessary to ensure a high level of protection of the subjects enrolled in such studies. Such information should be communicated to the other Member States.

(47) This Regulation should only cover clinical performance studies which pursue regulatory purposes laid down in this Regulation.

(48) In order to better protect health and safety regarding devices on the market, the vigilance system for *in vitro* diagnostic medical devices should be made more effective by creating a central portal at Union level for reporting serious incidents and field safety corrective actions ***within and outside the Union***. **[Am. 26]**

(49) ***Member States should take all necessary measures to raise awareness among healthcare professionals, users and patients about the importance of reporting incidents.*** Healthcare professionals, ***users*** and patients should be empowered ***and enabled*** to report ~~suspected serious~~ incidents at national level using harmonised formats~~. The~~ ***and guaranteeing anonymity, where appropriate***. ***In order to minimise the recurrence of such incidents, the*** national competent authorities should inform manufacturers ***and, if appropriate, their subsidiaries and sub-contractors,*** and ~~share~~ ***report*** the information ~~with their peers~~ ***via the respective electronic system in Eudamed*** when they confirm that ~~a serious~~ ***an*** incident has occurred ~~in order to minimise recurrence of those incidents~~. **[Am. 27]**

(50) The assessment of reported serious incidents and field safety corrective actions should be conducted at national level but coordination should be ensured where similar incidents have occurred or field safety corrective actions have to be carried out in more than one Member State, with the objective of sharing resources and ensuring consistency regarding the corrective action.

(51) The reporting of serious adverse events during interventional clinical performance studies and other clinical performance studies involving risks for the subjects, and the reporting of serious incidents occurring after an *in vitro* diagnostic medical device has been placed on the market should be clearly distinguished to avoid double reporting.

(52) Rules on market surveillance should be included in this Regulation to reinforce the rights and obligations of the national competent authorities, to ensure effective coordination of their market surveillance activities and to clarify the applicable procedures.

(53) The Member States ~~shall~~ ***should*** levy fees for the designation and monitoring of notified bodies to ensure sustainability of the monitoring of those bodies by Member States and to establish a level playing field for notified bodies. ***These fees should be comparable across Member States and should be made public.*** **[Am. 28]**

(54) Whilst this Regulation should not affect the right of the Member States to levy fees for activities at national level, Member States should inform the Commission and the other Member States before they adopt the ***comparable*** level and structure of the fees to ensure transparency. **[Am. 29]**

(54a) Member States should adopt provisions on standard fees for notified bodies, which should be comparable across Member States. The Commission should provide guidelines to facilitate the comparability of those fees. Member States should transmit their list of standard fees to the Commission and ensure that the notified bodies registered on their territory make the lists of standard fees for their conformity assessment activities publicly available. **[Am. 30]**

(55) ~~An expert committee, the Medical Device Coordination Group~~ ***A*** MDCG, composed of persons designated by the Member States, based on their role and expertise in the field of medical devices and *in vitro* diagnostic medical devices, should be established in accordance with the conditions and modalities defined in Article 78 of Regulation (EU) .../...[Ref. of future Regulation on medical devices] on medical devices[1] to fulfil the tasks conferred on it by this Regulation and by Regulation (EU) .../... [Ref. of future Regulation on medical devices] on medical devices, to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation. ***Prior to taking up their duties, members of the MDCG should make available a declaration of commitment and a declaration of interests indicating either the absence of any interests which could be considered prejudicial to their independence or any direct or indirect interests which could be prejudicial to their independence. Those declarations should be verified by the Commission.*** **[Am. 31]**

1 OJ L […], […], p. […]

(56) Closer coordination between national competent authorities through information exchange and coordinated assessments under the direction of a coordinating authority is fundamental for ensuring a uniform high level of health and safety within the internal market, in particular in the areas of clinical performance studies and vigilance. This should also lead to more efficient use of scarce resources at national level.

(57) The Commission should provide scientific, technical and corresponding logistic support to the coordinating national authority and ensure that the regulatory system for *in vitro* diagnostic medical devices is effectively implemented at Union level based on sound scientific evidence.

(58) The Union should actively participate in international regulatory cooperation in the field of *in vitro* diagnostic medical devices to facilitate the exchange of safety-related information regarding *in vitro* diagnostic medical devices and foster the further development of international regulatory guidelines promoting the adoption of regulations in other jurisdictions with a level of health and safety protection equivalent to that set by this Regulation.

(59) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and notably human dignity, the integrity of the person, ***the principle of free and informed consent of the person concerned,*** the protection of personal data, the freedom of art and science, the freedom to conduct business and the right to property***, as well as the European Convention on Human Rights and Biomedicine as well as the Additional Protocol to that Convention concerning Genetic Testing for Health Purposes***. This Regulation should be applied by the Member States in accordance with those rights and principles. **[Am. 32]**

(59a) Clear rules on the application of DNA tests are important. It is however advisable to regulate only on some basic elements and leave room for the Member States for more specific regulation in this area. Member States should for example regulate, that all devices providing an indication of a genetic disease which develops in adulthood or affects family planning may not be used on minors unless preventive treatment is available. **[Am. 33]**

(59b) While genetic counselling should be mandatory in specific cases it should not be mandatory in cases where a diagnosis of a patient already suffering from a disease is confirmed by a genetic test or where a companion diagnostic is used. **[Am. 34]**

(59c) This Regulation is in keeping with the United Nations Convention on the Rights of Persons with Disabilities of 13 December 2006, ratified by the European Union on 23 December 2010, pursuant to which the signatories commit themselves, in particular, to promote, protect and guarantee the full and equal exercise of all human rights and basic freedoms by all persons with disabilities and to promote the respect of their inherent dignity, inter alia by raising awareness about the abilities of disabled persons and the contribution they make. **[Am. 35]**

(59d) Whereas, in view of the need to protect the integrity of the human person during the sampling, collection and use of substances derived from the human body, it is appropriate to apply the principles laid down in the Convention of the Council of Europe for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine. **[Am. 270]**

(60) In order to maintain a high level of health and safety, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect ~~of the adaptation to technical progress of the general safety and performance requirements, of the elements to be addressed in the technical documentation, of the minimum content of the EU declaration of conformity and of the certificates issued by notified bodies~~, of the minimum requirements to be met by notified bodies, of the classification rules, ~~of the conformity assessment procedures~~, and of the documentation to be submitted for the approval of clinical performance studies; the establishment of the UDI system; the information to be submitted for the registration of *in vitro* diagnostic medical devices and certain economic operators; the level and structure of fees for the designation and monitoring of notified bodies; the publicly available information in respect of clinical performance studies; the adoption of preventive health protection measures at EU level; and the tasks of and criteria for European Union reference laboratories and the level and structure of fees for scientific opinions delivered by them. ***However, basic aspects elements of this Regulation such as general safety and performance requirements, elements to be addressed in technical documentation, the minimum content of the Union declaration of conformity, amending or supplementing the conformity assessment procedures, should only be amended through the ordinary legislative procedure***. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council. **[Am. 36]**

(61) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[1].

(62) The advisory procedure should be used for the adoption of the form and presentation of the data elements of the manufacturers' summary of safety and performance, of the codes defining the notified bodies' scopes of designation and of the model for certificates of free sale, given that those acts have a procedural character and do not directly impact the health and safety at Union level.

(63) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the extension to the territory of the Union of a national derogation from the applicable conformity assessment procedures in exceptional cases; relating to the Commission's position whether a provisional national measure against an *in vitro* diagnostic medical device presenting a risk or a provisional national preventive health protection measure is justified or not; and relating to the adoption of a Union measure against an *in vitro* diagnostic medical device presenting a risk, imperative grounds of urgency so require.

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1 Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

(64) To allow economic operators, ~~notified bodies, Member States and the Commission~~ ***especially SMEs,*** to adapt to the changes introduced by this Regulation ***and to ensure its proper application***, it is appropriate to provide for a sufficient transitional period ~~for that adaptation and for the~~ ***to allow for*** organisational arrangements ~~to be taken for its proper application~~***to be made. However, parts of the Regulation that concern Member States and the Commission should be implemented as soon as possible***. It is particularly important that ~~by the date of application,~~ a sufficient number of notified bodies ~~are designated~~ ***is designated*** in accordance with the new requirements, ***as soon as possible,*** to avoid any shortage of *in vitro* diagnostic medical devices on the market. **[Am. 37]**

(65) In order to ensure a smooth transition to the registration of *in vitro* diagnostic medical devices, ~~of relevant economic operators and of certificates, the obligation to submit the relevant information to~~ the electronic systems put in place by this Regulation at Union level should become ~~fully effective only 18 months after the date of application of this Regulation. During this transitional period, Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC should remain in force. However,~~ ***operational as soon as possible.*** Economic operators and notified bodies who register in the relevant electronic systems provided for at Union level should be considered in compliance with the registration requirements adopted by the Member States pursuant to those provisions of the Directive to avoid multiple registrations. **[Am. 38]**

(66) Directive 98/79/EC should be repealed to ensure that only one set of rules applies to the placing of *in vitro* diagnostic medical devices on the market and the related aspects covered by this Regulation.

(67) Since the objective of this Regulation, namely to ensure high standards of quality and safety for *in vitro* diagnostic medical devices, thus ensuring a high level of protection of health and safety of patients, users and other persons, cannot sufficiently be achieved by the Member States and can, by reason of the scale of the measure, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(67a) It is a long standing policy of the Union not to interfere with national policy allowing, prohibiting or limiting at national level ethically controversial technologies, such as pre-implantation genetic testing. This Regulation should not interfere with this principle, and the decision to allow, prohibit or restrict such technologies should therefore remain at national level. Where a Member State allows such technologies whether with or without restriction, the standards laid down in this Regulation should apply. **[Am. 39]**

(67b) Although internationally certified reference materials and materials used for external quality assessment schemes are not covered by this Regulation, calibrators and control materials needed by the user to establish or verify performances of devices are in vitro diagnostic medical devices. **[Am. 272]**

HAVE ADOPTED THIS REGULATION:

Chapter I

Scope and definitions

Article 1

Scope

1. This Regulation establishes rules to be complied with by in vitro diagnostic medical devices and accessories to in vitro diagnostic medical devices that are placed on the market or put into service in the Union for human use.

   For the purposes of this Regulation, *in vitro* diagnostic medical devices and accessories to *in vitro* diagnostic medical devices shall hereinafter be referred to as 'devices'.

2. This Regulation shall not apply to:

   (a) products for general laboratory use, unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination;

   (b) invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen;

(c) higher metrological order reference materials.

3. Any device which, when placed on the market or used in accordance with the manufacturer's instructions, incorporates as an integral part a medical device as defined in Article 2 of Regulation (EU) .../... [Ref. of future Regulation on medical devices] on medical devices without being an *in vitro* diagnostic medical device, shall be governed by this Regulation, provided that the principal intended purpose of the combination is that of an *in vitro* diagnostic medical device referred to in Article 2(2) of this Regulation. The relevant general safety and performance requirements set out in Annex I to Regulation (EU) .../... [Ref. of future Regulation on medical devices] shall apply as far as the safety and performance of the medical device part that is not an *in vitro* diagnostic medical device are concerned.

4. This Regulation is a specific Union legislation within the meaning of Article 1(4) of Directive 2004/108/EC and within the meaning of Article 3 of Directive 2006/42/EC.

5. This Regulation shall not affect the application of Directive 96/29/Euratom, nor of Directive 97/43/Euratom.

6. This Regulation ***provides that certain devices may only be supplied on a medical prescription but*** it shall not affect national laws which require that certain ***other*** devices may also only be supplied on a medical prescription. ***Direct to consumer advertising of devices classed as prescription only by this Regulation shall be illegal.***

The following devices may only be supplied on a medical prescription:

1) Class D devices;

2) Class C devices in the following categories:

(a) devices for genetic testing;

(b) companion diagnostics.

By derogation, justified by the attainment of a high level of public health protection, Members States may maintain or introduce national provisions allowing special class D tests to also be available without a medical prescription. In that case, they shall duly inform the Commission.

The Commission shall be empowered to adopt delegated acts in accordance with Article 85 to decide that other class C tests may only be supplied on a medical prescription after consultation with stakeholders. **[Am. 268]**

7. References to a Member State in this Regulation shall be understood as including any other country with which the Union has concluded an agreement which confers on that country the same status as a Member State for the purpose of application of this Regulation.

7a. The regulation of in-vitro diagnostic medical devices at Union level shall not interfere with the freedom of Member States to decide whether to restrict the use of any specific type of in-vitro diagnostic device in relation to aspects that are not covered by this Regulation. **[Am. 41]**

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

Definitions related to devices:

(1) ‘medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific ***direct or indirect*** medical purposes of:

- diagnosis, prevention, monitoring, ***prediction, prognosis,*** treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological process or state,
- control or support of conception,
- disinfection or sterilisation of any of the above-mentioned products,
- ***providing information concerning direct or indirect impacts on health,***

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means. **[Ams 42 and 43]**

(2) '*in vitro* diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

– concerning a physiological or pathological state;

– concerning ~~a~~ congenital ~~abnormality~~***physical or mental impairments***; **[Am. 44]**

– concerning the predisposition to a medical condition or a disease;

– to determine the safety and compatibility with potential recipients;

– to predict treatment response or reactions;

– to define or monitor therapeutic measures.

Specimen receptacles are considered to be *in vitro* diagnostic medical devices. For the purposes of this Regulation, ‘specimen receptacle’ means devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination.

In vitro diagnostic medical devices used for DNA-testing shall be subject to this Regulation. **[Am. 45]**

(3) 'accessory to an *in vitro* diagnostic medical device' means an article which, whilst not being an *in vitro* diagnostic medical device, is intended by its manufacturer to be used together with one or several particular *in vitro* diagnostic medical device(s) to specifically enable or assist the *in vitro* diagnostic medical device(s) to be used in accordance with its/their intended purpose(s);

(4) 'device for self-testing' means any device intended by the manufacturer to be used by lay persons***, including testing services offered to lay persons by means of information society services***; **[Am. 46]**

(5) 'device for near-patient testing' means any device that is not intended for self-testing but is intended to perform testing outside a laboratory environment, generally near to, or at the side of, the patient;

(6) 'companion diagnostic' means a device specifically intended ~~to select~~ ***for and essential to the selection of*** patients with a previously diagnosed condition or predisposition as ~~eligible~~ ***suitable or unsuitable*** for a ~~targeted~~ ***specific*** therapy ***with a medicinal product or a range of medicinal products***; **[Am. 47]**

(7) 'generic device group' means a set of devices having the same or similar intended purposes or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;

(8) 'single-use device' means a device that is intended to be used on an individual patient during a single procedure;

The single procedure may involve several uses or prolonged use on the same patient.

(9) 'intended purpose' means the use for which the device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements;

(10) 'label' means the written, printed, or graphic information appearing either on the device itself, or on the packaging of each unit, or on the packaging of multiple devices;

(11) 'instructions for use' means the information provided by the manufacturer to inform the user of the device's intended purpose and proper use and of any precautions to be taken;

(12) 'Unique Device Identification' ('UDI') means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market;

(12a) 'novel device' means:

– ***a device which incorporates technology (the analyte, technology or test platform) not previously used in diagnostics, or;***

– ***an existing device which is being used for a new intended purpose for the first time;*** **[Am. 48]**

(12b) ‘ device for genetic testing’ means an in vitro diagnostic medical device the purpose of which is to identify a genetic characteristic of a person which is inherited or acquired during prenatal development; **[Am. 49]**

Definitions related to the making available of devices:

(13) 'making available on the market' means any supply of a device, other than a device for performance evaluation, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(14) 'placing on the market' means the first making available of a device, other than a device for performance evaluation, on the Union market;

(15) 'putting into service' means the stage at which a device, other than a device for performance evaluation, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;

(15a) 'Information society service' means any service, normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services;
[Am. 50]

Definitions related to economic operators, users and specific processes:

(16) 'manufacturer' means the natural or legal person ~~who manufactures or~~ ***with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under that person's own name, regardless of whether those operations are carried out by that person or on that person's behalf by a third party. The obligations of this Regulation to be met by manufacturers also apply to natural or legal persons who assemble, package, process,*** fully ~~refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device~~ ***refurbish or label one or more ready-made products and/or assign to them their intended purpose as devices with a view to their being placed on the market*** under ~~his~~ ***that person's own*** name or trademark.
[Am. 51]

For the purposes of the definition of manufacturer, fully refurbishing is defined as the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it in conformity with this Regulation, combined with the assignment of a new lifetime to the refurbished device;

(17) 'authorised representative' means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer to act on his behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;

(18) 'importer' means any natural or legal person established within the Union who places a device from a third country on the Union market;

(19) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the market;

(20) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;

(21) 'health institution' means an organisation whose primary purpose is the care or treatment of patients ~~or the promotion of public health~~ ***and which has the legal capacity to carry out such activities***; ***commercial laboratories which provide diagnostic services shall not be considered to be health institutions***; **[Am. 52]**

(22) 'user' means any healthcare professional or lay person who uses a device;

(23) 'lay person' means an individual who does not have formal education in a relevant field of healthcare or medical discipline;

Definitions related to conformity assessment:

(24) 'conformity assessment' means the process demonstrating whether the requirements of this Regulation relating to a device have been fulfilled;

(25) 'conformity assessment body' means a body that performs third-party conformity assessment activities including ~~calibration~~, testing, certification and inspection; **[Am. 53]**

(26) 'notified body' means a conformity assessment body designated in accordance with this Regulation;

(27) 'CE marking of conformity' or 'CE marking' means a marking by which the manufacturer indicates that the device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing;

Definitions related to clinical evidence:

(28) 'clinical evidence' means the ~~information that supports~~ ***data, positive and negative, supporting the evaluation of*** the scientific validity and performance for the use of a device as intended by the manufacturer; **[Am. 54]**

(29) 'scientific validity of an analyte' means the association of an analyte to a clinical condition or a physiological state;

(30) 'performance of a device' means the ability of a device to achieve its intended purpose as claimed by the manufacturer. It consists of ~~the~~ ***attainment of technical capabilities,*** analytical ***performance*** and, where applicable, the clinical performance supporting the intended purpose of the device; **[Am. 55]**

(31) 'analytical performance' means the ability of a device to correctly detect or measure a particular analyte;

(32) 'clinical performance' means the ability of a device to yield results that are correlated with a particular clinical condition or a physiological state in accordance with the target population and intended user;

(33) 'clinical performance study' means a study undertaken to establish or confirm the clinical performance of a device;

(34) 'clinical performance study protocol' means the document(s) setting out the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the clinical performance study;

(35) 'performance evaluation' means the assessment and analysis of data to establish or verify ~~the~~ ***that the device performs as intended by the manufacturer, including the technical,*** analytical and, where applicable, the clinical performance of a device; **[Am. 56]**

(36) 'device for performance evaluation' means a device intended by the manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analyses or in other appropriate environments outside the manufacturer's own premises. Devices intended to be used for research purposes, without any medical objective, are not regarded as devices for performance evaluation;

(37) 'interventional clinical performance study' means a clinical performance study where the test results may influence patient management decisions and/or may be used to guide treatment;

(37a) 'ethics committee' means an independent body in a Member State, consisting of health-care professionals and non-medical members including at least one well-experienced, knowledgeable patient or patient representative. Its responsibility is to protect the rights, safety, physical and mental integrity, dignity and well-being of subjects involved in interventional clinical performance studies and other clinical performance studies involving risk for the subject and to provide public assurance of that protection in full transparency. In cases of such studies involving minors, the ethics committee shall include at least one healthcare professional with paediatric expertise. **[Am. 57]**

(38) 'diagnostic specificity' means the ability of a device to recognize the absence of a target marker associated with a particular disease or condition;

(39) 'diagnostic sensitivity' means the ability of a device to identify the presence of a target marker associated with a particular disease or condition;

(40) 'predictive value' means the probability that a person with a positive device test result has a given condition under investigation, or that a person with a negative device test result does not have a given condition;

(41) 'positive predictive value' means the ability of a device to separate true positive results from false positive results for a given attribute in a given population;

(42) 'negative predictive value' means the ability of a device to separate true negative results from false negative results for a given attribute in a given population;

(43) 'likelihood ratio' means the likelihood that a given result would be expected in an individual with the target clinical condition or physiological state compared to the likelihood that the same result would be expected in an individual without that clinical condition or physiological state;

(43a) 'calibrator' means a measurement standard used in the calibration of a device; **[Am. 58]**

(44) '~~calibrators and~~ control ~~materials~~ ***material***" means ~~any~~ ***a*** substance, material or article intended by ~~the~~ ***its*** manufacturer ~~either to establish measurement relationships or~~ ***to be used*** to verify the performance characteristics of a device ~~in conjunction with the intended purpose of that device~~; **[Am. 59]**

(45) 'sponsor' means any individual, company, institution or organisation which takes responsibility for the initiation and management***, conduct or financing*** of a clinical performance study; **[Am. 60]**

(46) 'adverse event' means any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons in the context of a clinical performance study, whether or not related to the device for performance evaluation;

(47) 'serious adverse event' means any adverse event that led to any of the following:

– death,

– serious deterioration in the health of the subject, that resulted in any of the following:

(i) life-threatening illness or injury,

(ii) permanent impairment of a body structure or a body function,

(iii) hospitalisation or ~~extending the duration of~~ ***prolongation of patient*** hospitalisation, **[Am. 61]**

(iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,

– foetal distress, foetal death or a congenital abnormality or birth defect.

(48) 'device deficiency' means any inadequacy in the identity, quality, ~~durability~~ ***stability***, reliability, safety or performance of a device for performance evaluation, including malfunction, use errors or inadequacy in the information supplied by the manufacturer; **[Am. 62]**

(48a) 'inspection' means an official review, carried out by a competent authority, of documents, facilities, records, quality assurance arrangements, and any other resources that are deemed by that authority to be related to a clinical performance study and that may be located at the site of the trial, at the sponsor's and/or contract research organisation's facilities, or at other establishments which the competent authority sees fit to inspect; **[Am. 63]**

Definitions related to vigilance and market surveillance:

(49) 'recall' means any measure aimed at achieving the return of a device that has already been made available to the end user;

(50) 'withdrawal' means any measure aimed at preventing a device in the supply chain from further being made available on the market;

(51) 'incident' means any malfunction or deterioration in the characteristics or performance of a device made available on the market, any inadequacy in the information supplied by the manufacturer and any unexpected undesirable effect;

(52) 'serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following:

- death of a patient, user or other person,
- temporary or permanent serious deterioration of the patient's, user's or other person's state of health,
- serious public health threat;

(53) 'corrective action' means action taken to eliminate the cause of a potential or real non-conformity or other undesirable situation;

(54) 'field safety corrective action' means corrective action taken by the manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market;

(55) 'field safety notice' means the communication sent by the manufacturer to users***, waste disposal operators*** or customers in relation to a field safety corrective action; **[Am. 64]**

(56) 'market surveillance' means the activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;

(56a) 'unannounced inspection' means an inspection conducted without advance notice; **[Am. 65]**

Definitions related to standards and other technical specifications:

(57) ‘harmonised standard’ means a European standard as defined in Article 2(1)(c) of Regulation (EU) No .../... [Ref. of future Regulation on European standardisation];

(58) 'common technical specifications’ means a document other than a standard that prescribes technical requirements that provide a means to comply with the legal obligations applicable to a device, process or system.

Article 3

Regulatory status of products

~~1.~~ The Commission may ***on its own initiative or shall*** at the request of a Member State ~~or on its own initiative~~, by means of implementing acts ***on the basis of the opinions of the MDCG and the MDAC referred to in Articles 76 and 76a respectively***, determine whether or not a specific product, or category or group of products, ***including borderline products,*** falls within the definitions of an *in vitro* diagnostic medical devices or of an accessory to an *in vitro* diagnostic medical device. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

~~2. The Commission shall ensure the sharing of expertise between Member States in the fields of *in vitro* diagnostic medical devices, medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products in order to determine the appropriate regulatory status of a product, or category or group of products.~~ **[Am. 66]**

~~SECTION 1~~ CHAPTER II

CLASSIFICATION OF IN VITRO DIAGNOSTIC MEDICAL DEVICES [AM. 135]

Article 39

Classification of in vitro diagnostic medical devices

1. Devices shall be divided into class A, B, C and D, taking into account their intended purpose***, novelty, complexity*** and inherent risks. Classification shall be carried out in accordance with the classification criteria set out in Annex VII. **[Am. 136]**

2. Any dispute between the manufacturer and the notified body concerned, arising from the application of the classification criteria, shall be referred for a decision to the competent authority of the Member State where the manufacturer has his registered place of business. In cases where the manufacturer has no registered place of business in the Union and has not yet designated an authorised representative, the matter shall be referred to the competent authority of the Member State where the authorised representative referred to in the last indent of point (b) of Section 3.2. of Annex VIII has his registered place of business.

   At least 14 days prior to any decision, the competent authority shall notify the MDCG and the Commission of its envisaged decision. ***That decision shall be made publicly available in the European databank***. **[Am. 137]**

3. The Commission may~~,~~ ***on its own initiative or shall*** at the request of a Member State ~~or on its own initiative~~, by means of implementing acts, decide on the application of the classification criteria set out in Annex VII to a given device, or category or group of devices with a view to determining their classification. ***Such a decision shall in particular be taken in order to resolve divergent decisions as regards the classification of devices between Member States.*** **[Am. 138]**

   Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

4. In the light of technical progress and any information which becomes available in the course of the vigilance and market surveillance activities described in Articles 59 to 73, the Commission***, having consulted relevant stakeholders, including healthcare professionals' organisations, and manufacturers' associations,*** shall be empowered to adopt delegated acts in accordance with Article 85 as regards the following: **[Am. 139]**

   (a) deciding that a device, or category or group of devices, should, by way of derogation from the classification criteria set out in Annex VII, be classified in another class,

   (b) amending or supplementing the classification criteria set out in Annex VII.

Chapter ~~V~~*VIII*

~~Classification and conformity~~ *Conformity* assessment [Am. 134]

SECTION 2 – CONFORMITY ASSESSMENT

Article 40

Conformity assessment procedures

1. Prior to placing a device on the market, manufacturers shall undertake an assessment of the conformity of that device. The conformity assessment procedures are set out in Annexes VIII to X.

2. Manufacturers of devices classified as class D, other than devices for performance evaluation, shall be subject to a conformity assessment based on full quality assurance, design dossier examination and batch verification, as specified in Annex VIII. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex IX, coupled with a conformity assessment based on production quality assurance including batch verification, as specified in Annex X.

In addition, where a reference laboratory is designated in accordance with Article 78, the notified body performing the conformity assessment shall request that reference laboratory to verify ***by laboratory testing*** compliance of the device with the applicable CTS, ~~when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as specified in Section 5.4 of Annex VIII and in Section 3.5 of Annex IX~~ ***as specified in Section 5.4 of Annex VIII and in Section 3.5 of Annex IX. Laboratory tests performed by a reference laboratory shall focus on, in particular, analytic sensitivity and specificity using reference materials and diagnostic sensitivity and specificity using specimens from early and established infection***.

[Am. 140]

For companion diagnostics intended to be used to assess the patient eligibility for treatment with a specific medicinal product, the notified body shall consult one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC of the European Parliament and of the Council[1] or the European Medicines Agency (EMA) in accordance with the procedures set out in Section 6.2 of Annex VIII and in Section 3.6 of Annex IX.

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1 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

3. Manufacturers of devices classified as class C, other than devices for performance evaluation, shall be subject to a conformity assessment based on full quality assurance, as specified in Annex VIII, with assessment of the design documentation within the technical documentation on a representative basis. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination, as specified in Annex IX coupled with conformity assessment based on production quality assurance, as specified in Annex X.

In addition, for devices for self-testing and near-patient testing, the manufacturer shall fulfil the supplementary requirements set out in Section 6.1 of Annex VIII or in Section 2 of Annex IX.

For companion diagnostic intended to be used to assess the patient eligibility to a treatment with a specific medicinal product, the notified body shall consult one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or the European Medicines Agency (EMA) in accordance with the procedures set out in Section 6.2 of Annex VIII and in Section 3.6 of Annex IX.

4. Manufacturers of devices classified as class B, other than devices for performance evaluation, shall be subject to a conformity assessment based on full quality assurance, as specified in Annex VIII.

In addition, for devices for self-testing ~~and near-patient testing~~, the manufacturer shall fulfil the supplementary requirements set out in Section 6.1 of Annex VIII. **[Am. 141]**

5. Manufacturers of devices classified as class A, other than devices for performance evaluation, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 15, after drawing up the technical documentation set out in Annex II.

However, if the devices are intended for near-patient testing, or if they are placed on the market in sterile condition or have a measuring function, the manufacturer shall apply the procedures set out in Annex VIII or in Annex X. Involvement of the notified body shall be limited:

~~(a) in the case of devices for near-patient testing, to the requirements set out in Section 6.1 of Annex VIII,~~ **[Am. 142]**

(b) in the case of devices placed on the market in sterile condition, to the aspects of manufacture concerned with securing and maintaining sterile conditions,

~~(c) in the case of devices with a measuring function, to the aspects of manufacture concerned with the conformity of the devices with the metrological requirements.~~

[Am. 143]

6. Manufacturers may choose to apply a conformity assessment procedure applicable to devices of a higher class than the device in question.

7. Devices for performance evaluation shall be subject to the requirements set out in Articles 48 to 58.

8. The Member State in which the notified body is established may determine that all or certain documents, including the technical documentation, audit, assessment and inspection reports, relating to the procedures referred to in paragraphs 1 to 6 shall be available in an official Union language. Otherwise they shall be available in an official Union language acceptable to the notified body.

9. The Commission may, by means of implementing acts, specify the modalities and the procedural aspects with a view to ensuring harmonised application of the conformity assessment procedures by the notified bodies, for any of the following aspects:

– the frequency and the sampling basis of the assessment of the design documentation within the technical documentation on a representative basis as set out in Sections 3.3.(c) and 4.5 of Annex VIII, in the case of devices classified as class C;

– the minimum frequency of unannounced factory inspections and sample checks to be conducted by notified bodies in accordance with Section 4.4 of Annex VIII, taking into account the risk-class and the type of device;

– the frequency of samples of the manufactured devices or batches of devices classified as class D to be sent to a reference laboratory designated under Article 78 in accordance with Section 5.7 of Annex VIII and Section 5.1 of Annex X, or

– the physical, laboratory or other tests to be carried out by notified bodies in the context of sample checks, design dossier examination and type examination in accordance with Sections 4.4 and 5.3 of Annex VIII and Sections 3.2 and 3.3 of Annex IX.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

~~10. In the light of technical progress and any information which becomes available in the course of the designation or monitoring of notified bodies set out in Articles 26 to 38, or of the vigilance and market surveillance activities described in Articles 59 to 73, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the conformity assessment procedures set out in Annexes VIII to X.~~ **[Am. 144]**

Article 41

Involvement of notified bodies ***in conformity assessment procedures***

1. Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer ***of devices other than those listed in Article 41a(1),*** may apply to a notified body of his choice, provided that the body is notified for the conformity assessment activities, the conformity assessment procedures and the devices concerned. ***Where a manufacturer applies to a notified body located in a Member State other than the one where it is registered, the manufacturer shall inform its national authority responsible for notified bodies of the application.*** An application may not be lodged in parallel with more than one notified body for the same conformity assessment activity. **[Am. 145]**

2. The notified body concerned shall inform the other notified bodies of any manufacturer who withdraws his application prior to the notified body's decision regarding the conformity assessment.

3. The notified body may require any information or data from the manufacturer which is necessary in order to properly conduct the chosen conformity assessment procedure.

4. Notified bodies and the personnel of notified bodies shall carry out their conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of their conformity assessment activities, especially as regards persons or groups with an interest in the results of those activities.

SECTION 2A - ADDITIONAL PROVISIONS FOR THE CONFORMITY ASSESSMENT OF HIGH-RISK DEVICES: INVOLVEMENT OF SPECIAL NOTIFIED BODIES **[Am. 146]**

Article 41a

Involvement of special notified bodies in conformity assessment procedures of high-risk devices

1. ***Only special notified bodies (SNB) shall be entitled to conduct conformity assessments for class D devices.***

2. ***Applicant special notified bodies which consider they fulfil the requirements for special notified bodies referred to in Annex VI, point 3.6, shall submit their application to the EMA.***

3. ***The application shall be accompanied by the fee payable to the EMA to cover the costs relating to the examination of the application.***

4. ***The EMA shall select the special notified bodies among applicants, in accordance with requirements listed in Annex VI, and adopt its opinion on the authorisation to perform conformity assessments for devices referred to in paragraph 1 within 90 days and send it to the Commission.***

5. ***The Commission shall then publish the notification accordingly and the names of the special notified bodies.***

6. ***This notification shall become valid the day after its publication in the database of notified bodies developed and managed by the Commission. The published notification shall determine the scope of lawful activity of the special notified body.***

This notification shall be valid for five years and subject to renewal every five years, following a new application to the EMA.

7. ***The manufacturer of devices specified in paragraph 1 may apply to a special notified body of its choice, whose name appears in the electronic system of Article 41b.***

8. ***An application may not be lodged in parallel with more than one special notified body for the same conformity assessment activity.***

9. ***The special notified body shall notify the EMA and the Commission of applications for conformity assessments for devices specified in paragraph 1.***

10. ***Article 41(2), (3) and (4) apply to special notified bodies.*** **[Am. 147]**

Article 41b

Electronic system on special notified bodies

1. ***The Commission, in collaboration with the Agency, shall establish and regularly update an electronic registration system for:***

- ***the registration of applications and granted authorisations to perform conformity assessments as special notified bodies under this Section and to collate and process information on the name of the special notified bodies;***
- ***the exchange of information with national authorities; and***
- ***the publication of assessment reports.***

2. ***The information collated and processed in the electronic system which relates to special notified bodies shall be entered into the electronic registration system by the EMA.***

3. ***The information collated and processed in the electronic system and which relates to special notified bodies shall be accessible to the public.*** **[Am. 148]**

Article 41c

Network of special notified bodies

1. ***The EMA shall establish, host, coordinate and manage the network of special notified bodies.***

2. ***The network shall have the following objectives:***

(a) ***to help realise the potential of European cooperation regarding highly specialised medical technologies in the area of in vitro diagnostic medical devices;***

(b) ***to contribute to the pooling of knowledge regarding in vitro diagnostic medical devices;***

(c) ***to encourage the development of conformity assessment benchmarks and to help develop and spread best practice within and outside the network;***

(d) ***to help identify the experts in innovative fields;***

(e) to develop and update rules on conflicts of interest; and

(f) to find common answers to similar challenges concerning the conduct of conformity assessment procedures in innovative technologies.

3. Meetings of the network shall be convened whenever requested by at least two of its members or by the EMA. It shall meet at least twice a year. **[Am. 149]**

~~*Article 42*~~

~~*Mechanism for scrutiny of certain conformity assessments*~~

~~1. Notified bodies shall notify the Commission of applications for conformity assessments for devices classified as class D, with the exception of applications to supplement or renew existing certificates. The notification shall be accompanied by the draft instructions for use referred to in Section 17.3 of Annex I and the draft summary of safety and performance referred to in Article 24. In its notification the notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the MDCG.~~

2. Within 28 days of receipt of the information referred to in paragraph 1, the MDCG may request the notified body to submit a summary of the preliminary conformity assessment prior to issuing a certificate. Upon suggestion by any of its members or by the Commission, the MDCG shall decide on making such request in accordance with the procedure set out in Article 78(4) of Regulation [Ref. of future Regulation on medical devices]. In its request the MDCG shall indicate the scientifically valid health reason for having selected the specific file for submission of a summary of the preliminary conformity assessment. When selecting a specific file for submission, the principle of equal treatment shall be duly taken into account.

   Within 5 days after receipt of the request by the MDCG, the notified body shall inform the manufacturer thereof.

3. The MDCG may submit comments on the summary of the preliminary conformity assessment at the latest 60 days after submission of this summary. Within that period and at the latest 30 days after submission, the MDCG may request the submission of additional information that for scientifically valid grounds are necessary for the analysis of the notified body's preliminary conformity assessment. This may include a request for samples or an on-site visit to the manufacturer's premises. Until submission of the additional information requested, the period for comments referred to in the first sentence of this subparagraph shall be suspended. Subsequent requests for additional information from the MDCG shall not suspend the period for the submission of comments.

4. The notified body shall give due consideration to any comments received in accordance with paragraph 3. It shall convey to the Commission an explanation of how they have been taken into consideration, including any due justification for not following the comments received, and its final decision regarding the conformity assessment in question. The Commission shall immediately transmit this information to the MDCG.

5. Where deemed necessary for the protection of patient safety and public health, the Commission may determine, by means of implementing acts, specific categories or groups of devices, other than devices classified as class D, to which paragraphs 1 to 4 shall apply during a predefined period of time. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

   Measures pursuant to this paragraph may be justified only by one or more of the following criteria:

   (a) the novelty of the device or of the technology on which it is based and the significant clinical or public health impact thereof;

   (b) an adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in case of failure;

(c) an increased rate of serious incidents reported in accordance with Article 59 in respect of a specific category or group of devices;

(d) significant discrepancies in the conformity assessments carried out by different notified bodies on substantially similar devices;

(e) public health concerns regarding a specific category or group of devices or the technology on which they are based.

6. The Commission shall make a summary of the comments submitted in accordance with paragraph 3 and the outcome of the conformity assessment procedure accessible to the public. It shall not disclose any personal data or information of commercially confidential nature.

7. The Commission shall set up the technical infrastructure for the data-exchange by an electronic means between notified bodies and MDCG for the purposes of this Article.

8. The Commission, by means of implementing acts, may adopt the modalities and the procedural aspects concerning the submission and analysis of the summary of the preliminary conformity assessment in accordance with paragraphs 2 and 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3). **[Am. 150]**

Article 42a

Case-by-case assessment procedure for the conformity assessments of certain high-risk devices

1. *Special notified bodies shall notify the Commission of applications for conformity assessments for Class D devices, with the exception of applications to renew existing certificates. The notification shall be accompanied by the draft instructions for use referred to in Section 17.3 of Annex I and the draft summary of safety and clinical performance referred to in Article 24. In its notification the special notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the Coordination Group (CG) of the Assessment Committee for Medical Devices (ACMD), referred to in Article 76a. The CG shall immediately transmit the notification and the accompanying documents to the relevant sub-groups.*

2. *Within 20 days of receipt of the information referred to in paragraph 1, the CG may decide, upon the suggestion of at least three of the members of the relevant sub-groups of the ACMD or by the Commission, to request the special notified body to submit the following documents prior to issuing a certificate:*

   - *the summary of the preliminary conformity assessment;*

- ***the clinical evidence report and the clinical performance study report as referred to in Annex XII;***
- ***data obtained from the post-market follow-up referred to in Annex XII; and***
- ***any information regarding the marketing or not of the device in third countries and, where available, the results of evaluation conducted by competent authorities in those countries,***

The members of the relevant sub-groups of the ACMD shall decide on making such case-by-case requests notably on the basis of the following criteria:

(a) ***the novelty of the device or of the technology on which it is based and the significant clinical or public health impact thereof;***

(b) ***an adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in case of failure;***

(c) an increased rate of serious incidents reported in accordance with Article 61 in respect of a specific category or group of devices;

(d) significant discrepancies in the conformity assessments carried out by different special notified bodies on substantially similar devices.

In the light of technical progress and any information which becomes available, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing these criteria.

In its request the ACMD shall indicate the scientifically valid health reason for having selected the specific file.

In the absence of a request from the ACMD within 20 days of receipt of the information referred to in paragraph 1, the special notified body shall proceed with the conformity assessment procedure.

3. ***The ACMD, following the consultation of the relevant sub-groups, shall issue an opinion on the documents referred to in paragraph 2 at the latest 60 days after their submission. Within that period and at the latest 30 days after submission, the ACMD may request the submission of additional information that for scientifically valid grounds is necessary for the analysis of the special notified body's preliminary conformity assessment. This may include a request for samples or an on-site visit to the manufacturer's premises. Until submission of the additional information requested, the period for comments referred to in the first sentence of this paragraph shall be suspended. Subsequent requests for additional information from the ACMD shall not suspend the period for the submission of comments.***

4. ***In its opinion the ACMD may recommend modifications of the documents referred to in paragraph 2.***

5. ***The ACMD shall inform the Commission, the special notified body and the manufacturer of its opinion within five days of its adoption.***

6. ***Within 15 days after receipt of the opinion referred to in paragraph 5, the special notified body shall indicate whether or not it agrees with the opinion of the ACMD. In the latter case, it may give written notice to the ACMD that it wishes to request a re-examination of the opinion. In that case, the special notified body shall forward to the ACMD the detailed grounds for the request within 30 days after receipt of the opinion. The ACMD shall immediately transmit this information to the Commission***

Within 30 days following receipt of the grounds for the request, the ACMD shall re-examine its opinion. The reasons for the conclusion reached shall be annexed to the final opinion.

7. ***Within 15 days after its adoption, the ACMD shall send its final opinion to the Commission, the special notified body and the manufacturer.***

8. ***Within 15 days after receipt of the opinion referred to in paragraph 6 in case of agreement by the special notified body or of the final opinion as referred to in paragraph 7, the Commission shall prepare, on the basis of the opinion, a draft of the decision to be taken in respect of the examined application for conformity assessment. This draft decision shall include or make reference to the opinion referred to in paragraphs 6 and 7 as applicable. Where the draft decision is not in accordance with the ACMD opinion, the Commission shall annex a detailed explanation of the reasons for the differences.***

The draft decision shall be forwarded to the Member States, the special notified body and the manufacturer.

The Commission shall take a final decision in accordance with and within 15 days after the end of, the examination procedure referred to in Article 84(3).

9. ***Where deemed necessary for the protection of patient safety and public health, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 to determine, specific categories or groups of devices, other than devices referred to in paragraph 1, to which paragraphs 1 to 8 shall apply during a predefined period of time.***

Measures pursuant to this paragraph may be justified only by one or more of the criteria referred to in paragraph 2.

10. ***The Commission shall make a summary of the opinions referred to in paragraphs 6 and 7 accessible to the public. It shall not disclose any personal data or information of a commercially confidential nature.***

11. ***The Commission shall set up the technical infrastructure for the data-exchange by electronic means between special notified bodies and the ACMD and between the ACMD and itself for the purposes of this Article.***

12. The Commission, by means of implementing acts, may adopt the modalities and the procedural aspects concerning the submission and analysis of the documentation provided in accordance with this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

13. Special notified bodies shall notify the Commission of applications for conformity assessments for Class D devices, with the exception of applications to renew existing certificates. The notification shall be accompanied by the draft instructions for use referred to in Section 17.3 of Annex I and the draft summary of safety and clinical performance referred to in Article 24. In its notification the special notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the Coordination Group (CG) of the Assessment Committee for Medical Devices (ACMD), referred to in Article 76a. The CG shall immediately transmit the notification and the accompanying documents to the relevant sub-groups. **[Am. 151]**

Article 43

Certificates

1. The certificates issued by the notified bodies in accordance with Annexes VIII, IX and X shall be in an official Union language determined by the Member State in which the notified body is established or otherwise in an official Union language acceptable to the notified body. The minimum content of the certificates is set out in Annex XI.

2. The certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the manufacturer, the validity of the certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.

3. Where a notified body finds that requirements of this Regulation are no longer met by the manufacturer, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any restrictions on it unless compliance with such requirements is ensured by appropriate corrective measures taken by the manufacturer within an appropriate deadline set by the notified body. The notified body shall give the reasons for its decision.

4. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information on certificates issued by notified bodies. The notified body shall enter into the electronic system information regarding certificates issued, including amendments and supplements, and information regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates. This information shall be accessible to the public.

5. In the light of technical progress, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the minimum content of the certificates set out in Annex XI.

Article 44

Voluntary change of notified body

1. ~~In cases~~ Where a manufacturer ~~terminates~~ ***decides to terminate*** his contract with a notified body and enters into a contract with another notified body in respect of the conformity assessment of the same device, ***it shall inform its national authority responsible for notified bodies of this change.*** The modalities of the change of notified body shall be clearly defined in an agreement between the manufacturer, the outgoing notified body and the incoming notified body. This agreement shall address at least the following aspects: **[Am. 152]**

(a) the date of invalidity of certificates issued by the outgoing notified body;

(b) the date until which the identification number of the outgoing notified body may be indicated in the information supplied by the manufacturer, including any promotional material;

(c) the transfer of documents, including confidentiality aspects and property rights;

(d) the date as of which the incoming notified body assumes full responsibility for the conformity assessment tasks.

2. On their date of invalidity, the outgoing notified body shall withdraw the certificates it has issued for the device concerned.

Article 44a

Additional assessment procedure in extraordinary cases

1. ***Special notified bodies shall notify the Commission of applications for conformity assessments for Class D devices, where no CTS standard exists, with the exception of applications to renew or supplement existing certificates. The notification shall be accompanied by the draft instructions for use referred to in Section 17.3 of Annex I and the draft summary of safety and clinical performance referred to in Article 24. In its notification the special notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the Medical Device Coordination Group (MDCG) for an opinion. In making its opinion, the MDCG may seek a clinical assessment from the relevant experts of the Assessment Committee for Medical Devices (ACMD), referred to in Article 76a.***

2. ***Within 20 days of receipt of the information referred to in paragraph 1, the MDCG may decide to request the special notified body to submit the following documents prior to issuing a certificate:***

- ***the clinical evidence report and the clinical performance study report as referred to in Annex XII,***

- *data obtained from the post market follow-up referred to in Annex XII, and*
- *any information regarding the marketing or not of the device in third countries and, where available, the results of evaluation conducted by competent authorities in those countries,*

The members of the MDCG shall decide on making such a request on the basis of the following criteria:

(a) *the novelty of the device with possible major clinical or health impact*

(b) *an adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in case of failure;*

(c) *an increased rate of serious incidents reported in accordance with Article 61 in respect of a specific category or group of devices;*

In the light of technical progress and any information which becomes available, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing these criteria.

In its request the MDCG shall indicate the scientifically valid health reason for having selected the specific file.

In the absence of a request from the MDCG within 20 days of receipt of the information referred to in paragraph 1, the special notified body shall proceed with the conformity assessment procedure.

3. ***The MDCG, following the consultation of the ACMD shall issue a MDCG opinion on the documents referred to in paragraph 2 at the latest 60 days after its submission. Within that period and at the latest 30 days after submission, the ACMD through the MDCG may request the submission of additional information that for scientifically valid grounds are necessary for the analysis of the documents referred to in paragraph 2. This may include a request for samples or an on-site visit to the manufacturer's premises. Until submission of the additional information requested, the period for comments referred to in the first sentence of this paragraph shall be suspended. Subsequent requests for additional information from the MDCG shall not suspend the period for the submission of comments.***

4. ***In its opinion the MDCG shall take into account the clinical assessment of the ACMD. The MDCG may recommend modifications of the documents referred to in paragraph 2.***

5. ***The MDCG shall inform the Commission, the special notified body and the manufacturer of its opinion.***

6. ***Within 15 days after receipt of the opinion referred to in paragraph 5, the special notified body shall indicate whether or not it agrees with the opinion of the MDCG. In the latter case, it may give written notice to the MDCG that it wishes to request a re-examination of the opinion. In that case, the special notified body shall forward to the MDCG the detailed grounds for the request within 30 days after receipt of the opinion. The MDCG shall immediately transmit this information to the Commission***

Within 30 days following receipt of the grounds for the request, the MDCG shall re-examine its opinion. The reasons for the conclusion reached shall be annexed to the final opinion.

7. ***Immediately after its adoption, the MDCG shall send its final opinion to the Commission, the special notified body and the manufacturer.***

8. ***In case of a favourable MDCG opinion, the special notified body may proceed with the certification.***

   However if the favourable MDCG opinion is dependent on the application of specific measures (e.g. adaptation of the post-market clinical follow-up plan, certification with a time limit), the special notified body shall issue the certificate of conformity only on condition that those measures are fully implemented.

   Following the adoption of a favourable opinion, the Commission shall always explore the possibility of adopting, common technical standards for the device of group of devices concerned and adopt them where possible.

   In case of an unfavourable MDCG opinion, the special notified body shall not deliver the certificate of conformity. Nevertheless, the special notified body may submit new information in response to the explanation included in the MDCG assessment. If the new information is substantially different to that which has been previously submitted the MDCG shall reassess the application.

At the request of the manufacturer, the Commission shall organise a hearing allowing discussion on the scientific grounds for the unfavourable scientific assessment and any action that the manufacturer may take or data that may be submitted to address the MDCG concerns.

9. ***Where deemed necessary for the protection of patient safety and public health, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 to determine, specific categories or groups of devices, other than devices referred to in paragraph 1, to which paragraphs 1 to 8 shall apply during a predefined period of time.***

Measures pursuant to this paragraph may be justified only by one or more of the criteria referred to in paragraph 2.

10. ***The Commission shall make a summary of the opinion referred to in paragraphs 6 and 7 accessible to the public. It shall not disclose any personal data or information of a commercially confidential nature.***

11. ***The Commission shall set up the technical infrastructure for the data-exchange by electronic means between the MDCG, the special notified bodies and the ACMD and between the ACMD and itself for the purposes of this Article.***

12. ***The Commission, by means of implementing acts, may adopt the modalities and the procedural aspects concerning the submission and analysis of the documentation provided in accordance with this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).***

13. ***The company concerned shall not be charged for the additional costs due to this assessment.*** **[Ams 259 and 269]**

Article 45

Derogation from the conformity assessment procedures

1. By way of derogation from Article 40, any competent authority may authorise, on duly justified request, the placing on the market or putting into service, within the territory of the Member State concerned, of a specific device for which the procedures referred to in Article 40 have not been carried out and use of which is in the interest of public health or patient safety.

2. The Member State shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of a device in accordance with paragraph 1 where such authorisation is granted for use other than for a single patient.

3. Upon request by a Member State and where this is in the interest of public health or patient safety in more than one Member State, the Commission may, by means of implementing acts, extend for a determined period of time the validity of an authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the device may be placed on the market or put into service. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

   On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 84(4).

Article 46

Certificate of free sale

1. For the purpose of export and upon request by a manufacturer, the Member State in which the manufacturer has its registered place of business shall issue a certificate of free sale declaring that the manufacturer is properly established and that the device in question bearing the CE marking in accordance with this Regulation may be legally marketed in the Union. The certificate of free sale shall be valid for the period indicated on it which shall not exceed five years and shall not exceed the validity of the certificate referred to in Article 43 issued for the device in question.

2. The Commission may, by means of implementing acts, establish a model for certificates of free sale taking into account international practice as regards the use of certificates of free sale. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 84(2).

Chapter IV

Notified Bodies

Article 26

National authorities responsible for notified bodies

1. A Member State that intends to designate a conformity assessment body as a notified body, or has designated a notified body, to carry out third-party conformity assessment tasks under this Regulation shall designate an authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, including subcontractors or subsidiaries of those bodies, hereinafter referred to as the 'national authority responsible for notified bodies'.

2. The national authority responsible for notified bodies shall be established, organised and operated so as to safeguard the objectivity and impartiality of its activities and to avoid any conflicts of interest with conformity assessment bodies.

3. It shall be organised so that each decision relating to notification of a conformity assessment body is taken by personnel different from those who carried out the assessment of the conformity assessment body.

4. It shall not perform any activities that conformity assessment bodies perform nor provide consultancy services on a commercial or competitive basis.

5. The national authority responsible for notified bodies shall safeguard the ~~confidentiality~~ ***confidential aspects*** of the information it obtains. However, it shall exchange information on a notified body with other Member States and the Commission. **[Am. 104]**

6. The national authority responsible for notified bodies shall have a sufficient number of ***permanent and*** competent personnel ~~at its disposal~~ ***"in-house",*** for the proper performance of its tasks. ***Compliance with that requirement shall be assessed in the peer-review referred to in paragraph 8.***

In particular, the personnel of the national authority responsible for auditing the work of personnel of notified bodies in charge of carrying out product related reviews shall have proven qualifications equivalent to those of the personnel of the notified bodies as laid down in point 3.2.5. of Annex VI.

Similarly, the personnel of the national authority responsible for auditing the work of personnel of notified bodies in charge of carrying out audits of the manufacturer's quality management system shall have proven qualifications equivalent to those of the personnel of the notified bodies as laid down in point 3.2.6. of Annex VI.

~~Without prejudice to Article 31(3), where~~ ***Where*** a national authority is responsible for the designation of notified bodies in the field of products other than *in vitro* diagnostic medical devices, the competent authority for *in vitro* diagnostic medical devices shall be consulted on all aspects specifically related to such devices. **[Am. 105]**

7. ***The ultimate responsibility for the notified bodies and the national authority responsible for notified bodies lies with the Member State in which they are located. The Member State shall check that the designated national authority responsible for notified bodies performs its work on the assessment, designation and notification of conformity assessment bodies and for the monitoring of the notified bodies properly and that the designated national authority responsible for notified bodies works impartially and objectively.*** Member States shall provide the Commission and the other Member States with ***all*** information ***they request*** on their procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and of any changes thereto. ***Such information shall be publicly available subject to Article 80.*** **[Am. 106]**

8. The national authority responsible for notified bodies shall be peer-reviewed every second year. The peer-review shall include an on-site visit to a conformity assessment body or a notified body under the responsibility of the reviewed authority. In the case referred to in the second subparagraph of paragraph 6, the competent authority for medical devices shall participate in the peer-review.

The Member States shall draw up the annual plan for the peer-review, ensuring an appropriate rotation in respect of reviewing and reviewed authorities, and submit it to the Commission. The Commission ~~may~~ ***shall*** participate in the review. The outcome of the peer-review shall be communicated to all Member States ~~and to the Commission~~ and a summary of the outcome shall be made publicly available. **[Am. 107]**

Article 27

Requirements relating to notified bodies

1. Notified bodies shall satisfy the organisational and general requirements and the quality management, resource and process requirements that are necessary to fulfil their tasks for which they are designated in accordance with this Regulation. ***In this respect, permanent "in-house" administrative, technical and scientific personnel, with medical, technical and, where needed, pharmacological knowledge shall be ensured. Permanent "in-house" personnel shall be used, but notified bodies may hire external experts on an ad hoc and temporary basis as and when needed.*** Minimum requirements to be met by notified bodies are set out in Annex VI. ***In particular, in accordance with point 1.2. of Annex VI , the notified body shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities and avoid conflict of interests.***

The notified body shall publish a list of its staff responsible for the conformity assessment and certification of medical devices. This list shall at least contain the qualifications, CV and declaration of interests for each member of staff. The list shall be sent to the national authority responsible for notified bodies which shall check that the staff satisfy the requirements of this Regulation. The list shall also be sent to the Commission. **[Am. 108]**

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the minimum requirements in Annex VI, in the light of technical progress and considering the minimum requirements needed for the assessment of specific devices, or categories or groups of devices

Article 28

Subsidiaries and subcontracting

-1. Notified bodies shall have permanent "in-house" competent personnel and expertise, both in technical fields linked with the assessment of the performance of the devices, and in the medical field. They shall have the capacity to evaluate "in-house" the quality of subcontractors.

Contracts may be awarded to external experts for the assessment of in vitro diagnostic medical devices or technologies in particular where clinical expertise is limited.

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the relevant requirements set out in Annex VI and shall inform the national authority responsible for notified bodies accordingly.

2. Notified bodies shall take full responsibility for the tasks performed on their behalf by subcontractors or subsidiaries.

2a. Notified bodies shall make publicly available the list of subcontractors or subsidiaries, the specific tasks for which they are responsible and the declarations of interest of their personnel.

3. Conformity assessment activities may be subcontracted or carried out by a subsidiary only with the ***explicit*** agreement of the legal or natural person that applied for conformity assessment.

4. ***At least once a year,*** notified bodies shall ~~keep at the disposal of~~ ***submit to*** the national authority responsible for notified bodies the relevant documents concerning the verification of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.

4a. The annual assessment of notified bodies as provided for in Article 33(3) shall include verification of the compliance of the subcontractor(s) or the subsidiary/ies of notified bodies with the requirements set out in Annex VI. **[Am. 109]**

Article 28a

Electronic system on registration of subsidiaries and subcontractors

1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information on subcontractors and subsidiaries, as well as on the specific tasks for which they are responsible.

2. ***Before subcontracting can effectively take place, the notified body which intends to subcontract specific tasks connected with conformity assessment or have recourse to a subsidiary for specific tasks connected with conformity assessment, shall register their name(s) together with their specific tasks.***

3. ***Within one week of any change occurring in relation to the information referred to in paragraph 1, the relevant economic operator shall update the data in the electronic system.***

4. ***The data contained in the electronic system shall be accessible to the public.*** **[Am. 110]**

Article 29

Application by a conformity assessment body for notification

1. A conformity assessment body shall submit an application for notification to the national authority responsible for notified bodies of the Member State in which it is established.

In the event that a conformity assessment body wants to be notified for devices referred to in Article 41a(1), it shall indicate so and submit an application for notification to the EMA in accordance with Article 41a(2) **[Am. 111]**

2. The application shall specify the conformity assessment activities, the conformity assessment procedures and the devices for which the body claims to be competent, supported by documentation proving compliance with all the requirements set out in Annex VI.

   In respect of the organisational and general requirements and the quality management requirements set out in Sections 1 and 2 of Annex VI, the relevant documentation may be submitted in form of a valid certificate and the corresponding evaluation report delivered by a national accreditation body in accordance with Regulation (EC) No 765/2008. The conformity assessment body shall be presumed to be in conformity with the requirements covered by the certificate delivered by such accreditation body.

3. After being designated, the notified body shall update the documentation referred to in paragraph 2 whenever relevant changes occur in order to enable the national authority responsible for notified bodies to monitor and verify continuous compliance with all the requirements set out in Annex VI.

Article 30

Assessment of the application

1. The national authority responsible for notified bodies shall check that the application referred to in Article 29 is complete and draw up a preliminary assessment report.

2. It shall submit the preliminary assessment report to the Commission which shall immediately transmit it to the Medical Device Coordination Group ('MDCG') referred to in Article 76. Upon request by the Commission, the report shall be submitted by the authority in up to three official Union languages.

3. Within 14 days of the submission referred to in paragraph 2, the Commission shall designate a joint assessment team made up of at least ~~two~~ ***three*** experts chosen from a list of experts who are qualified in the assessment of conformity assessment bodies ***and free of conflicts of interest with the applicant conformity assessment body***. The list shall be drawn up by the Commission in cooperation with the MDCG. At least one of these experts shall be a representative of the Commission ~~who~~***, and at least one other shall come from a Member State other than the one in which the applicant conformity assessment body is established. The Commission representative*** shall lead the joint assessment team. ***In case the conformity assessment body has asked to be notified for devices referred to in Article 41 a(1) , the EMA shall also be part of the joint assessment team.*** **[Am. 112]**

4. Within 90 days after designation of the joint assessment team, the national authority responsible for notified bodies and the joint assessment team shall review the documentation submitted with the application in accordance with Article 29 and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or sub-contractor, located inside or outside the Union, to be involved in the conformity assessment process. Such on-site assessment shall not cover requirements for which the applicant conformity assessment body has received a certificate delivered by the national accreditation body as referred to in Article 29(2), unless the Commission representative mentioned in Article 30(3) requests the on-site assessment.

Findings regarding non-compliance of ~~a~~ ***an applicant conformity assessment*** body with the requirements set out in Annex VI shall be raised during the assessment process and discussed between the national authority responsible for notified bodies and the joint assessment team ~~with a view to finding common agreement with respect to the assessment of the application. Divergent opinions shall be identified in~~. ***The national authority shall set out in the assessment report the measures that the notified body shall take to ensure compliance by that applicant conformity assessment body with the requirements set out in Annex VI. In the event of a disagreement, a separate opinion drawn up by the assessment team setting out its reservations regarding notification shall be appended to*** the assessment report of the national authority responsible. **[Am. 113]**

5. The national authority responsible for notified bodies shall submit its assessment report and its draft notification to the Commission which shall immediately transmit those documents to the MDCG and to the members of the joint assessment team. ***If the assessment team draws up a separate opinion, that too shall be submitted to the Commission for forwarding to the MDCG.*** Upon request by the Commission, those documents shall be submitted by the authority in up to three official Union languages. **[Am. 114]**

6. The joint assessment team shall provide its ***final*** opinion regarding the assessment report ~~and~~***,*** the draft notification ***and, where appropriate, the separate opinion drawn up by the assessment team,*** within 21 days of receipt of those documents and the Commission shall immediately submit this opinion to the MDCG. Within 21 days after receipt of the opinion of the joint assessment team, the MDCG shall issue a recommendation with regard to the draft notification ~~which the~~. ***The*** relevant national authority shall ~~duly take into consideration for~~ ***base*** its decision on the designation of the notified body ***on the recommendation by the MDCG. Where its decision differs from the MDCG recommendation, the relevant national authority shall provide the MDCG in writing all the necessary justifications for its decision***. **[Am. 115]**

7. The Commission may, by means of implementing acts, adopt measures setting out the modalities for the application for notification referred to in Article 29 and the assessment of the application set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

Article 31

Notification procedure

1. Member States shall notify the Commission and the other Member States of the conformity assessment bodies they have designated, using the electronic notification tool developed and managed by the Commission.

2. Member States ~~may~~ ***shall*** notify only conformity assessment bodies which satisfy the requirements set out in Annex VI ***and for which the application assessment procedure has been completed in accordance with Article 30.*** **[Am. 116]**

~~3. Where a national authority responsible for notified bodies is responsible for designation of notified bodies in the field of products other than *in vitro* diagnostic medical devices, the competent authority for *in vitro* diagnostic medical devices shall provide, prior to the notification, a positive opinion on the notification and its scope.~~ **[Am. 117]**

4. The notification shall clearly specify the scope of the designation indicating the conformity assessment activities, the conformity assessment procedures, the ***risk class and the*** type of devices which the notified body is authorised to assess. **[Am. 118]**

   The Commission may, by means of implementing acts, set up a list of codes and the corresponding types of devices to define the scope of the designation of notified bodies which the Member States shall indicate in their notification. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 84(2).

5. The notification shall be accompanied by the final assessment report of the national authority responsible for notified bodies, the opinion of the joint assessment team and the recommendation of the MDCG. Where the notifying Member State does not follow the recommendation of the MDCG, it shall provide a duly substantiated justification.

6. The notifying Member State shall provide the Commission and the other Member States with documentary evidence regarding the arrangements in place to ensure that the notified body will be monitored regularly and will continue to satisfy the requirements set out in Annex VI. It shall furthermore submit evidence of the availability of competent personnel for monitoring the notified body in accordance with Article 26(6).

7. Within 28 days of a notification, a Member State or the Commission may raise written objections, setting out its arguments, with regard either to the notified body or to its monitoring by the national authority responsible for notified bodies.

8. When a Member State or the Commission raises objections in accordance with paragraph 7, the effect of the notification shall be ***immediately*** suspended. In this case, the Commission shall bring the matter before the MDCG within 15 days after expiry of the period referred to in paragraph 7. After consulting the parties involved, the MDCG shall give its opinion at the latest within 28 days after the matter has been brought before it. If the notifying Member State does not agree with the opinion of the MDCG, it may request the Commission to give its opinion. **[Am. 119]**

9. Where no objection is raised in accordance with paragraph 7 or where the MDCG or the Commission, after having been consulted in accordance with paragraph 8, is of the opinion that the notification may be accepted fully ~~or partially~~, the Commission shall publish the notification accordingly.

The Commission shall also enter information on the notification of the notified body into the electronic system referred to in the second subparagraph of Article 25. That information shall be accompanied by the final assessment report of the national authority responsible for notified bodies, the opinion of the joint assessment team and the recommendation of the MDCG, as referred to in this article.

The full details of the notification, including the class and the typology of devices, as well as the annexes, shall be made publicly available. **[Am. 120]**

10. The notification shall become valid the day after its publication in the database of notified bodies developed and managed by the Commission. The published notification shall determine the scope of lawful activity of the notified body.

Article 32

Identification number and list of notified bodies

1. The Commission shall assign an identification number to each notified body for which the notification is accepted in accordance with Article 31. It shall assign a single identification number even when the body is notified under several Union acts.

2. The Commission shall make ***easily*** accessible to the public the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified ***and all documents for the notification procedure as referred to in Article 31(5)***. The Commission shall ensure that the list is kept up to date. **[Am. 121]**

Article 33

Monitoring of notified bodies

1. The national authority responsible for notified bodies***, and where applicable the EMA,*** shall continuously monitor the notified bodies to ensure ongoing compliance with the requirements set out in Annex VI. The notified bodies shall, on request, supply all relevant information and documents, required to enable the authority to verify compliance with those criteria.

   Notified bodies shall, without delay, ***and within 15 days at the latest***, inform the national authority responsible for notified bodies of any changes, in particular regarding their personnel, facilities, subsidiaries or subcontractors, which may affect compliance with the requirements set out in Annex VI or their ability to conduct the conformity assessment procedures relating to the devices for which they have been designated.

2. Notified bodies shall respond without delay ***and within 15 days at the latest,*** to requests relating to conformity assessments they have carried out, submitted by their or another Member State's authority or by the Commission. The national authority responsible for notified bodies of the Member State in which the body is established shall enforce requests submitted by authorities of any other Member State or by the Commission ~~***unless***~~***. Where*** there is a legitimate reason for not doing so ~~in which case both sides may~~ ***the notified bodies shall explain these reasons in writing and shall*** consult the MDCG~~. The notified body or their national authority responsible for notified bodies may request that any information transmitted to the authorities of another Member State or to the Commission shall be treated as confidential~~***, which shall then issue a recommendation. The national authority responsible for notified bodies shall comply with the MDCG's recommendation***.

3. At least once a year, the national authority responsible for notified bodies shall assess whether each notified body under its responsibility still satisfies the requirements set out in Annex VI***, including an assessment of whether its subcontractor(s) and subsidiary/-ies satisfy those requirements.*** This assessment shall include an ***unannounced inspection through an*** on-site visit to each notified body***, and to each subsidiary or subcontractor within or outside the Union, if relevant***.

The assessment shall also include a review of samples of the design dossier assessments carried out by the notified body to determine the ongoing competence of the notified body and quality of its assessments, in particular the notified body's ability to evaluate and assess clinical evidence.

4. ~~Three~~ ***Two*** years after notification of a notified body, and again every ~~third~~ ***second*** year thereafter, the assessment to determine whether the notified body body ***and its subsidiaries and subcontractors*** still ~~satisfies~~ ***satisfy*** the requirements set out in Annex VI shall be conducted by the national authority responsible for notified bodies of the Member State in which the body is established and a joint assessment team designated in accordance with the procedure described in Article 30(3) and (4). At the request of the Commission or of a Member State, the MDCG may initiate the assessment process described in this paragraph at any time when there is reasonable concern about the ongoing compliance of a notified body, ***or a subsidiary or subcontractor of a notified body,*** with the requirements set out in Annex VI.

For special notified bodies under Article 41a, the assessment referred to in this paragraph shall be performed every year.

The comprehensive results of the assessments shall be published.

5. The Member States shall report to the Commission and to the other Member States, at least once a year, on their monitoring activities. This report shall contain a summary which shall be made publicly available.

5a. Every year, the notified bodies shall forward an annual activity report setting out the information referred to in Annex VI, point 5 to the competent authority and to the Commission, which shall forward it to the MDCG. **[Am. 122]**

Article 34

Changes to notifications

1. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification. The procedures described in Article 30(2) to (6) and in Article 31 shall apply to changes where they entail extension of the scope of the notification. In all other cases, the Commission shall immediately publish the amended notification in the electronic notification tool referred to in Article 31(10).

2. Where a national authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in Annex VI, or that it is failing to fulfil its obligations, the authority shall suspend, restrict, or fully or partially withdraw the notification, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. ~~A~~ ***Suspension shall apply until a decision to annul the*** suspension ***has been reached by the MDCG, which*** shall ~~not exceed a period of one year, renewable once for the same period~~ ***follow an assessment by a joint assessment team designated in accordance with the procedure described in Article 30(3)***. Where the notified body has ceased its activity, the national authority responsible for notified bodies shall withdraw the notification.

The national authority responsible for notified bodies shall immediately ***and within 10 days at the latest***, inform the Commission ~~and~~***,*** the other Member States ***and the relevant manufacturers and health professionals*** of any suspension, restriction or withdrawal of a notification. **[Am. 123]**

3. In the event of restriction, suspension or withdrawal of a notification, the Member State shall ***inform the Commission and shall*** take appropriate steps to ensure that the files of the notified body concerned are either processed by another notified body or kept available for the national authorities responsible for notified bodies and for market surveillance at their request. **[Am. 124]**

4. The national authority responsible for notified bodies shall assess whether the reasons which gave rise to the ~~change to~~ ***suspension, restriction or withdrawal of*** the notification have an impact on the certificates issued by the notified body and, within three months after having notified the changes to the notification, shall submit a report on its findings to the Commission and the other Member States. Where necessary to ensure the safety of devices on the market, that authority shall instruct the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, ***and at the latest 30 days after the publication of the report***, any certificates which were unduly issued. If the notified body fails to do so within the determined period of time, or has ceased its activity, the national authority responsible for notified bodies itself shall suspend or withdraw the certificates unduly issued.

With a view to verifying whether the reasons for the suspension, restriction or withdrawal of the notification have implications for the certificates issued, the national authority responsible shall ask the relevant manufacturers to supply evidence of conformity at notification, and the manufacturers shall have 30 days in which to respond to that request. **[Am. 125]**

5. The certificates, other than those unduly issued, which were issued by the notified body for which the notification has been suspended, restricted or withdrawn shall remain valid in the following circumstances:

(a) in the case of suspension of a notification: on condition that, within three months of the suspension~~, either the competent authority for *in vitro* diagnostic medical devices of the Member State in which the manufacturer of the device covered by the certificate is established, or~~ another notified body responsible for *in vitro* diagnostic medical devices confirms in writing that it is assuming the functions of the notified body during the period of suspension;

(b) in the case of restriction or withdrawal of a notification: for a period of three months after the restriction or withdrawal. The competent authority for *in vitro* diagnostic medical devices of the Member State in which the manufacturer of the device covered by the certificate is established may extend the validity of the certificates for further periods of three months, which altogether may not exceed twelve months, provided it is assuming the functions of the notified body during this period.

The authority or the notified body assuming the functions of the notified body affected by the change of notification shall immediately ***and within 10 days at the latest***, inform the Commission, the other Member States and the other notified bodies thereof.

The Commission shall immediately and within 10 days at the latest enter information on the changes to the notification of the notified body into the electronic system referred to in the second paragraph of Article 25. **[Am. 126]**

Article 35

Challenge to the competence of notified bodies

1. The Commission shall investigate all cases where concerns have been brought to its attention regarding the continued fulfilment by a notified body of the requirements set out in Annex VI or the obligations to which it is subject. It may also commence such investigations on its own initiative***, including the unannounced inspection of the notified body by a joint assessment team whose composition meets the conditions set out in Article 30(3)***. **[Am. 127]**

2. The notifying Member State shall provide the Commission, on request, with all information regarding the notification of the notified body concerned.

3. Where the Commission ~~ascertains~~***, in consultation with the MDCG, decides*** that a notified body no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including the suspension, restriction or withdrawal of the notification***,*** if necessary***, in line with Article 34(2)***. **[Am. 128]**

Where the Member State fails to take the necessary corrective measures, the Commission may, by means of implementing acts, suspend, restrict or withdraw the notification. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3). It shall notify the Member State concerned of its decision and update the database and list of notified bodies.

Article 36

Exchange of experience between national authorities responsible for notified bodies

The Commission shall provide for the organisation of exchange of experience and coordination of administrative practice between the national authorities responsible for notified bodies under this Regulation.

Article 37

Coordination of notified bodies

The Commission***, in consultation with the MDCG,*** shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of the coordination group of notified bodies referred to in Article 39 of Regulation [Ref. of future Regulation on medical devices]. ***This group shall meet on a regular basis and at least twice a year.*** **[Am. 129]**

The bodies notified under this Regulation shall participate in the work of that group.

The Commission or the MDCG may request the participation of any notified body. **[Am. 130]**

The Commission may, by means of implementing acts, adopt measures setting out the modalities for the functioning of the coordination group of notified bodies as set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3). **[Am. 131]**

Article 38

Fees ***for the activities of national authorities***

1. The Member State where the bodies are established shall levy fees on applicant conformity assessment bodies and on notified bodies. These fees shall, wholly or partly, cover the costs relating to the activities exercised by the national authorities responsible for notified bodies in accordance with this Regulation.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 setting out the structure and the level of the fees referred to in paragraph 1, taking into account the objectives of protection of human health and safety, support of innovation ~~and~~, cost-effectiveness ***and the need to create a level-playing field across Member States***. Particular attention shall be paid to the interests of notified bodies that submitted a valid certificate delivered by the national accreditation body as referred to in Article 29(2) and notified bodies that are small and medium-sized enterprises as defined by Commission Recommendation 2003/361/EC[1].

These fees shall be proportionate and consistent with national standards of living. The level of fees shall be made public. **[Am. 132]**

Article 38a

Transparency on fees charged by notified bodies for conformity assessment activities

1. Member States shall adopt provisions on standard fees for notified bodies.

2. Fees shall be comparable across Member States. The Commission shall provide guidelines to facilitate comparability of those fees by … [*] ***.***

3. Member States shall transmit their list of standard fees to the Commission.

4. The national authority shall ensure that the notified bodies make the lists of standard fees for the conformity assessment activities publicly available. **[Am. 133]**

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1 OJ L 124, 20.5.2003, p. 36.

* ***24 months from the date of entry into force of this Regulation.***

Chapter ~~VI~~*V*

Clinical evidence [Am. 153]

Article 47

General requirements regarding clinical evidence

1. The demonstration of conformity with the general safety and performance requirements set out in Annex I, under normal conditions of use, shall be based on clinical evidence, ***or additional safety data for general safety and performance requirements not covered by clinical evidence.*** **[Am. 154]**

2. The clinical evidence shall support the intended purpose of the device as stated by the manufacturer.

3. The clinical evidence shall include all the information supporting the scientific validity of the analyte, the analytical performance and, where applicable, the clinical performance of the device, as described in Section 1 of Part A of Annex XII.

3a. Where the manufacturer claims and/or describes a clinical use, evidence attesting to that use shall constitute part of the requirements. **[Am. 155]**

4. Where demonstration of conformity with the general safety and performance requirements based on clinical performance data or parts thereof is not deemed appropriate, adequate justification for any such exception shall be given based on the results of the manufacturer's risk management and on consideration of the characteristics of the device and, in particular, its intended purpose(s), the intended performance and the claims of the manufacturer. The adequacy of demonstration of conformity with the general safety and performance requirements based on the results of analytical performance evaluation alone shall be duly substantiated in the technical documentation referred to in Annex II.

Exemption from demonstration of conformity with general safety and performance requirements based on clinical data under the first subparagraph shall be subject to prior approval by the competent authority. **[Am. 156]**

5. The scientific validity data, the analytical performance data and, where applicable, the clinical performance data shall be summarised as part of a clinical evidence report referred to in Section 3 of Part A of Annex XII. The clinical evidence report shall be included ~~or fully referenced~~ in the technical documentation referred to in Annex II relating to the device concerned. **[Am. 157]**

6. The clinical evidence and its documentation shall be updated throughout the life cycle of the device concerned with data obtained from implementation of the manufacturer's post-market surveillance plan referred to in Article 8(6).

7. The manufacturer shall ensure that the device for performance evaluation complies with the general requirements of this Regulation apart from the aspects covered by the performance evaluation and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the patient, user and other persons.

   The manufacturer shall undertake to keep available to the competent authorities and the EU reference laboratories the documentation allowing an understanding of the design, manufacture and performances of the device, including its expected performance, so as to allow assessment of conformity with the requirements of this Regulation. This documentation shall be kept for at least five years after the performance evaluation of the device in question has ended.

Article 48

General requirements regarding clinical performance studies

1. Clinical performance studies shall be subject to this Regulation if they are conducted for one or more of the following purposes:

   (a) to verify that, under normal conditions of use, the devices are designed, manufactured and packaged in such a way that they are suitable for one or more of the specific purposes of an *in vitro* diagnostic medical device referred to in number (2) of Article 2, and achieve the performance intended as specified by the manufacturers ***or sponsor***; **[Am. 158]**

   (b) to verify ~~that devices achieve~~ ***the clinical safety and efficacy of the device, including*** the intended benefits to the patient ~~as specified by the manufacturer~~***, when used for the intended purpose, in the target population and in accordance with the instructions of use***; **[Am. 159]**

   (c) to determine any limits to the performance of the devices, under normal conditions of use.

2. Clinical performance studies shall be performed in circumstances similar to the normal conditions of use of the device.

3. Where the sponsor is not established in the Union, he shall ensure that a contact person is established in the Union. That contact person shall be the addressee for all communications with the sponsor provided for in this Regulation. Any communication to that contact person shall be considered as communication to the sponsor.

4. All clinical performance studies shall be designed and conducted in a way that the rights, safety and well-being of the subjects participating in such clinical performance studies are protected and that the clinical data generated in the clinical performance study are going to be reliable and robust. ***Such studies shall not be conducted if the risks associated with the investigation are not medically justifiable in terms of the potential benefits of the device.*** **[Am. 160]**

5. All clinical performance studies shall be designed, conducted, recorded and reported in accordance with Section 2 of Annex XII.

6. For interventional clinical performance studies, as defined in number (37) of Article 2, and for other clinical performance studies, where the conduct of the study, including specimen collection, involves invasive procedures or other risks for the subjects of the studies, the requirements set out in Articles 49 to 58 and in Annex XIII shall apply, in addition to the obligations laid down in this Article. ***The Commission shall be empowered to adopt delegated acts in accordance with Article 85 concerning the provision of a list with negligible risks, which allows a derogation to be made from the relevant Article.***
[Am. 161]

Article 49

Application for interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies

1. Before making the first application, the sponsor shall procure from the electronic system referred to in Article 51 a single identification number for a clinical performance study conducted in one site or multiple sites, in one or more than one Member State. The sponsor shall use this single identification number when registering the clinical performance study in accordance with Article 50.

2. The sponsor of a clinical performance study shall submit an application to the Member State(s) in which the study is to be conducted accompanied by the documentation referred to in Annex XIII. Within ~~six~~ ***14*** days after receipt of the application, the Member State concerned shall notify the sponsor whether the clinical performance study falls within the scope of this Regulation and whether the application is complete.

In case of more than one Member State concerned, where a Member State disagrees with the coordinating Member State on whether the clinical performance study should be approved, on grounds other than intrinsically national, local or ethical concerns, the Member States concerned shall make an attempt to agree on a conclusion. If no conclusion is found, the Commission shall take a decision after having consulted the Member States concerned, and if appropriate, having taken advice from the MDCG.

In cases where the Member States concerned object to the clinical performance study for intrinsically national, local or ethical concerns, the clinical performance study should not take place in the Member States concerned. **[Am. 162]**

Where the Member State has not notified the sponsor within the time period referred to in the first subparagraph, the clinical performance study shall be considered as falling within the scope of this Regulation and the application shall be considered complete.

3. Where the Member State finds that the clinical performance study applied for does not fall within the scope of this Regulation or that the application is not complete, it shall inform the sponsor thereof and shall set a maximum of ~~six~~ ***ten*** days for the sponsor to comment or to complete the application. **[Am. 163]**

   Where the sponsor has not provided comments nor completed the application within the time-period referred to in the first subparagraph, the application shall be considered as withdrawn.

   Where the Member State has not notified the sponsor according to paragraph 2 within ~~three~~ ***seven*** days following receipt of the comments or of the completed application, the clinical performance study shall be considered as falling within the scope of this Regulation and the application shall be considered complete. **[Am. 164]**

4. For the purposes of this Chapter, the date on which the sponsor is notified in accordance with paragraph 2 shall be the validation date of the application. Where the sponsor is not notified, the validation date shall be the last day of the time periods referred to in paragraphs 2 and 3.

5. The sponsor may start the clinical performance study in the following circumstances:

(a) in the case of devices for performance evaluation classified as class C or D, as soon as the Member State concerned has notified the sponsor of its approval;

(b) in the case of devices for performance evaluation classified as class A or B immediately after the date of application, provided that the Member State concerned has so decided and that evidence is provided that the rights, safety and well-being of the subjects to the clinical performance study are protected;

(c) after the expiry of ~~35~~ ***60*** days after the validation date referred to in paragraph 4, unless the Member State concerned has notified the sponsor within that period of its refusal based on considerations of public health, patient safety or public policy.
[Am. 165]

5a. Member States shall ensure that a clinical performance study is suspended, cancelled or temporarily interrupted if in the light of new facts it would no longer be approved by the competent authority or if it would no longer receive a favourable opinion from the ethics committee. **[Am. 166]**

6. Member States shall ensure that the persons assessing the application do not have conflicts of interest and that they are independent of the sponsor, the institution of the study site(s) and the investigators involved, as well as free of any other undue influence.

Member States shall ensure that the assessment is done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience. In the assessment, the view of at least one person whose primary area of interest is non-scientific shall be taken into account. The view of at least one patient shall be taken into account.

6a. Every step in the clinical performance study, from first consideration of the need and justification for the study to the publication of the results, shall be carried out in accordance with recognised ethical principles, such as those laid down in the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects adopted by the 18th World Medical Assembly in Helsinki in 1964 and last amended by the 59th World Medical Association General Assembly in Seoul in 2008.

6b. Authorisation by the Member State concerned for conducting a clinical performance study under this Article shall be granted only after examination and approval by an independent ethics committee in accordance with the World Medical Association's Declaration of Helsinki.

6c. ***The examination of the ethics committee shall cover in particular the medical justification for the study, the consent of the test subjects participating in the clinical performance study following the provision of full information about the clinical performance study and the suitability of the investigators and investigation facilities.***

The ethics committee shall act in accordance with the respective laws and regulations of the country or countries in which the study is to be conducted and shall abide by all relevant international norms and standards. It shall also work with such efficiency as to enable the Member State concerned to comply with the procedural deadlines set out in this Chapter.

The ethics committee shall be made up of an appropriate number of members, who together are in possession of the relevant qualifications and experience in order to be able to assess the scientific, medical and ethical aspects of the clinical investigation under scrutiny.

The members of the ethics committee assessing the application for a clinical performance study shall be independent from the sponsor, the institution of the performance study site, and the investigators involved, as well as free of any other undue influence. The names, qualifications, and declaration of interest of the assessors of the application shall be made publicly available.

6d. ***Member States shall take the necessary measures to establish ethics committees in the field of clinical performance studies where such committees do not exist, and to facilitate their work.***

6e. ***The Commission shall facilitate cooperation of ethics committees and the sharing of best practices on ethical issues including the procedures and principles of ethical assessment.***

The Commission shall develop guidelines on patient involvement in ethics committees, drawing upon existing good practices. **[Am. 167]**

7. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing, in the light of technical progress and global regulatory developments, the requirements for the documentation to be submitted with the application for the clinical performance study that is laid down in Chapter I of Annex XIII.

Article 49a

Supervision by Member States

1. ***Member States shall appoint inspectors to supervise compliance with this Regulation and shall ensure that those inspectors are adequately qualified and trained.***

2. ***Inspections shall be conducted under the responsibility of the Member State where the inspection takes place.***

3. ***Where a Member State intends to carry out an inspection with regard to one or several interventional clinical performance studies which are conducted in more than one Member State, it shall notify its intention to the other Member States concerned, the Commission and the EMA, through the Union portal, and shall inform them of its findings after the inspection.***

4. ***The MDCG shall coordinate cooperation on inspections between Member States and on inspections conducted by Member States in third countries.***

5. Following an inspection, the Member State under whose responsibility the inspection has been conducted shall draw up an inspection report. That Member State shall make the inspection report available to the sponsor of the relevant clinical trial and shall submit the inspection report through the Union portal to the Union database. When making the inspection report available to the sponsor, the Member State concerned shall ensure that confidentiality is protected.

6. The Commission shall specify the details for the arrangement of the inspection procedures by means of implementing acts in accordance with Article 85. **[Am. 168]**

Article 50

Registration of interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies

1. Before commencing the clinical performance study, the sponsor shall enter in the electronic system referred to in Article 51 the following information regarding the clinical performance study:

   (a) the single identification number of the clinical performance study;

(b) the name and contact details of the sponsor and, if applicable, his contact person established in the Union;

(c) the name and contact details of the natural or legal person responsible for the manufacture of the device for performance evaluation, if different from the sponsor;

(d) the description of the device for performance evaluation;

(e) the description of the comparator(s), if applicable;

(f) the purpose of the clinical performance study;

(g) the status of the clinical performance study.

(ga) the methodology to be used, the number of subjects involved and the intended result of the study. **[Am. 169]**

2. Within one week of any change occurring in relation to the information referred to in paragraph 1, the sponsor shall update the relevant data in the electronic system referred to in Article 51.

3. The information shall be accessible to the public, through the electronic system referred to in Article 51, unless, for all or parts of that information, confidentiality of the information is justified on any of the following grounds:

   (a) protection of personal data in accordance with Regulation (EC) No 45/2001,

   (b) protection of commercially sensitive information,

   (c) effective supervision of the conduct of the clinical performance study by the Member State(s) concerned.

4. No personal data of subjects participating in the clinical performance study shall be accessible to the public.

Article 51

Electronic system on interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies

1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system on interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies to create the single identification numbers for such clinical performance studies referred to in Article 49(1) and to collate and process the following information:

   (a) the registration of clinical performance studies in accordance with Article 50;

   (b) the exchange of information between the Member States and between them and the Commission in accordance with Article 54;

   (c) the information related to clinical performance studies conducted in more than one Member State in case of a single application in accordance with Article 56;

   (d) the reports on serious adverse events and device deficiencies referred to in Article 57(2) in case of single application in accordance with Article 56.

(da) the clinical performance study report and summary submitted by the sponsor in accordance with Article 55(3).

2. When setting up the electronic system referred in paragraph 1, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article […] of Regulation (EU) No .../... [Ref. of future Regulation on clinical trials]. With the exception of the information referred to in Article 50 ***and in points (d) and (da) of paragraph 1 of this Article***, the information collated and processed in the electronic system shall be accessible only to the Member States and to the Commission***. The Commission shall also ensure that healthcare professionals have access to the electronic system***.

The information referred to in points (d) and (da) of paragraph 1 of this Article shall be accessible to the public in accordance with Article 50(3) and (4).

2a. Upon a reasoned request, all information on a specific in vitro diagnostic medical device available in the electronic system shall be made accessible to the party requesting it, save where the confidentiality of all or parts of the information is justified in accordance with Article 50(3). **[Am. 170]**

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 determining which other information regarding clinical performance studies collated and processed in the electronic system shall be publicly accessible to allow interoperability with the EU database for clinical trials on medicinal products for human use set up by Regulation (EU) No .../... [Ref. of future Regulation on clinical trials]. Article 50(3) and (4) shall apply.

Article 52

Interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies with devices authorised to bear the CE marking

1. Where a clinical performance study is to be conducted to further assess devices which are authorised in accordance with Article 40 to bear the CE marking and within its intended purpose referred to in the relevant conformity assessment procedure, hereinafter referred to as 'post-market follow-up performance study', the sponsor shall notify the Member States concerned at least 30 days prior to their commencement if the study would submit subjects to additionally invasive or burdensome procedures. Articles 48(1) to (5), 50, 53, 54(1) and 55(1), the first subparagraph of Article 55(2) and the relevant provisions of Annexes XII and XIII shall apply.

2. If the aim of the clinical performance study regarding a device which is authorised in accordance with Article 40 to bear the CE marking is to assess such device for a purpose other than that referred to in the information supplied by the manufacturer in accordance with Section 17 of Annex I and in the relevant conformity assessment procedure, Articles 48 to 58 shall apply.

Article 53

Substantial modifications to interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies

1. If the sponsor introduces modifications to a clinical performance study that are likely to have a substantial impact on the safety or rights of the subjects or on the robustness or reliability of the clinical data generated by the study, he shall notify the Member State(s) concerned of the reasons for and the content of those modifications. The notification shall be accompanied by an updated version of the relevant documentation referred to in Annex XIII.

2. The sponsor may implement the modifications referred to in paragraph 1 at the earliest 30 days after notification, unless the Member State concerned has notified the sponsor of its refusal based on considerations of public health, patient safety or public policy.

Article 54

Information exchange between Member States on interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies

1. Where a Member State has refused, suspended or terminated a clinical performance study, or has called for a substantial modification or temporary halt of a clinical performance study, or has been notified by the sponsor of the early termination of a clinical performance study on safety ***or efficacy*** grounds, that Member State shall communicate ***such facts and*** its decision and the grounds ~~therefor~~ ***for that decision*** to all Member States and the Commission by means of the electronic system referred to in Article 51. **[Am. 171]**

2. Where an application is withdrawn by the sponsor prior to a decision by a Member State that Member State shall inform all the other Member States and the Commission of that fact, by means of the electronic system referred to in Article 51.

Article 55

Information by the sponsor in the event of temporary halt or termination of interventional clinical performance studies or of other clinical performance studies involving risks for the subjects of the studies

1. If the sponsor has temporarily halted a clinical performance study on safety ***or efficacy*** grounds, he shall inform the Member States concerned within 15 days of the temporary halt. **[Am. 172]**

2. The sponsor shall notify each Member State concerned of the end of a clinical performance study in relation to that Member State, providing a justification in the event of early termination***, so that all Member States can inform sponsors conducting similar clinical performance studies at the same time within the Union of the results of that clinical performance study***. That notification shall be made within 15 days from the end of the clinical performance study in relation to that Member State. **[Am. 173]**

   If the study is conducted in more than one Member State, the sponsor shall notify all Member States concerned of the overall end of the clinical performance study. ***Information on the reasons for the early termination of the clinical performance study shall also be provided to all Member States, so that all Member States can inform sponsors conducting similar clinical performance studies, at the same time within the Union, of the results of the clinical performance study.*** That notification shall be made within 15 days from the overall end of the clinical performance study. **[Am. 174]**

3. ~~Within~~ ***Irrespective of the outcome of the clinical performance study, within*** one year from the end of the clinical performance study ***or from its early termination***, the sponsor shall submit to the Member States concerned ~~a summary of~~ the results of the clinical performance study in form of a clinical performance study report referred to in Section 2.3.3 of Part A of Annex XII. ***It shall be accompanied by a summary presented in terms that are easily understandable to a layperson. Both the report and the summary shall be submitted by the sponsor by means of the electronic system referred to in Article 51.***

Where, for ***justified*** scientific reasons, it is not possible to submit the clinical performance study report within one year, it shall be submitted as soon as it is available. In this case, the clinical performance study protocol referred to in Section 2.3.2 of Part A of Annex XII shall specify when the results of the clinical performance study are going to be submitted, together with ~~an explanation~~ ***a justification***.

3a. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 in order to define the content and structure of the layperson's summary.

The Commission shall be empowered to adopt delegated acts in accordance with Article 85 in order to establish rules for the communication of the clinical performance study report.

For cases where the sponsor decides to share raw data on a voluntary basis, the Commission shall produce guidelines for the formatting and sharing of that data.
[Am. 175]

Article 56

Interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies conducted in more than one Member State

1. By means of the electronic system referred to in Article 51, the sponsor of the clinical performance study to be conducted in more than one Member State may submit, for the purpose of Article 49, a single application that, upon receipt, is transmitted electronically to the Member States concerned.

2. ~~In the single application, the sponsor shall propose one of~~ The Member States concerned ~~as coordinating Member State. If that Member State does not wish to be the coordinating Member State, it~~ shall agree, within six days of submission of the single application, ~~with another~~ ***which*** Member State ~~concerned that the latter~~ shall be the coordinating Member State. ~~If no other~~ Member ~~State accepts to be the coordinating Member State, the Member State proposed by the sponsor shall be the coordinating Member State. If another Member State than the one proposed by the sponsor becomes~~ ***States and the Commission shall agree, in the framework of the attributions of the Medical Devices Coordination Group, on clear rules for designating the*** coordinating Member State~~, the deadlines referred to in Article 49(2) shall start on the day following the acceptance~~. **[Am. 176]**

3. Under the direction of the coordinating Member State referred to in paragraph 2, the Member States concerned shall coordinate their assessment of the application, in particular of the documentation submitted in accordance with Chapter I of Annex XIII, except for Sections 4.2, 4.3 and 4.4 thereof which shall be assessed separately by each Member State concerned.

The coordinating Member State shall:

(a) within 6 days of receipt of the single application notify the sponsor whether the clinical performance study falls within the scope of this Regulation and whether the application is complete, except for the documentation submitted in accordance with Sections 4.2, 4.3 and 4.4 of Chapter I of Annex XIII for which each Member State shall verify the completeness. Article 49(2) to (4) shall apply to the coordinating Member State in relation to the verification that the clinical performance study falls within the scope of this Regulation and that the application is complete, except for the documentation submitted in accordance with Sections 4.2, 4.3 and 4.4 of Chapter I of Annex XIII. Article 49(2) to (4) shall apply to each Member State in relation to the verification that the documentation submitted in accordance with Sections 4.2, 4.3 and 4.4 of Chapter I of Annex XIII is complete;

(b) establish the results of the coordinated assessment in a report to be taken into account by the other Member States concerned when deciding on the sponsor's application in accordance with Article 49(5).

4. The substantial modifications referred to in Article 53 shall be notified to the Member States concerned by means of the electronic system referred to in Article 51. Any assessment as to whether there are grounds for refusal as referred to in Article 53 shall be carried out under the direction of the coordinating Member State.

~~5. For the purpose of Article 55(3), the sponsor shall submit the clinical performance study report to the Member States concerned by means of the electronic system referred to in Article 51.~~ **[Am. 177]**

6. The Commission shall provide secretarial support to the coordinating Member State in the accomplishment of its tasks provided for in this Chapter.

Article 57

Recording and reporting of events occurring during interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies

1. The sponsor shall fully record any of the following:

   (a) an adverse event identified in the clinical performance study protocol as critical to the evaluation of the results of the clinical performance study in view of the purposes referred to in Article 48(1);

(b) a serious adverse event;

(c) a device deficiency that might have led to a serious adverse event if suitable action had not been taken, intervention had not occurred, or circumstances had been less fortunate;

(d) new findings in relation to any event referred to in points (a) to (c).

2. The sponsor shall report to all Member States where a clinical performance study is conducted without delay any of the following:

(a) ~~a serious~~ ***any*** adverse event that has a causal relationship with the device for performance evaluation, the comparator or the study procedure or where such causal relationship is reasonably possible; **[Am. 178]**

(b) a device deficiency that might have led to a serious adverse event if suitable action had not been taken, intervention had not occurred, or circumstances had been less fortunate;

(c) new findings in relation to any event referred to in points (a) to (b).

The time period for reporting shall take account of the severity of the event. Where necessary to ensure timely reporting, the sponsor may submit an initial incomplete report followed up by a complete report.

3. The sponsor shall also report to the Member States concerned any event referred to in paragraph 2 occurring in third countries in which a clinical performance study is performed under the same clinical performance study protocol as the one applying to a clinical performance study covered by this Regulation.

4. In the case of a clinical performance study for which the sponsor has used the single application referred to in Article 56, the sponsor shall report any event as referred to in paragraph 2 by means of the electronic system referred to in Article 51. Upon receipt, this report shall be transmitted electronically to all Member States concerned.

Under the direction of the coordinating Member State referred to in Article 56(2), the Member States shall coordinate their assessment of serious adverse events and device deficiencies to determine whether a clinical performance study needs to be terminated, suspended, temporarily halted or modified.

This paragraph shall not affect the rights of the other Member States to perform their own evaluation and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating Member State and the Commission shall be kept informed of the outcome of any such evaluation and the adoption of any such measures.

5. In the case of post-market follow-up performance studies referred to in Article 52(1), the provisions on vigilance contained in Articles 59 to 64 shall apply instead of this Article.

Article 58

Implementing acts

The Commission may, by means of implementing acts, adopt the modalities and procedural aspects necessary for the implementation of this Chapter, as regards the following:

(a) harmonised forms for the application for clinical performance studies and their assessment as referred to in Articles 49 and 56, taking into account specific categories or groups of devices;

(b) the functioning of the electronic system referred to in Article 51;

(c) harmonised forms for the notification of post-market follow-up performance studies as referred to in Article 52(1), and of substantial modifications as referred to in Article 53;

(d) the exchange of information between Member States as referred to in Article 54;

(e) harmonised forms for the reporting of serious adverse events and device deficiencies as referred to in Article 57;

(f) the timelines for the reporting of serious adverse events and device deficiencies, taking into account the severity of the event to be reported as referred to in Article 57.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

Chapter ~~II~~*VI*

Making available *and application* of devices, obligations of economic operators, CE marking, free movement [Am. 67]

Article 4

Placing on the market and putting into service

1. A device may be placed on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.

2. A device shall meet the general safety and performance requirements which apply to it, taking into account its intended purpose. General safety and performance requirements are set out in Annex I.

3. Demonstration of conformity with the general safety and performance requirements shall ~~be based on~~ ***include*** clinical evidence in accordance with Article 47. **[Am. 68]**

4. Devices that are manufactured and used within a single health institution shall be considered as being put into service.

5. With the exception of Article 59(4), the requirements of this Regulation shall not apply to devices classified as class A, B and C, in accordance with the rules set out in Annex VII, and manufactured and used only within a single health institution, provided manufacture and use occur solely under the health institution's single quality management system, and the health institution is ~~compliant~~ ***accredited*** with standard EN ISO 15189 or any other equivalent recognised standard. ***However, the requirements of this Regulation shall continue to apply to clinical or commercial pathology laboratories which do not have health care (i.e. care and treatment of patients) or the promotion of public health as their primary purpose.*** Member States ~~may~~ ***shall*** require that the health institutions submit to the competent authority a list of such devices which have been manufactured and used on their territory and ~~may~~ ***shall*** make the manufacture and use of the devices concerned subject to further safety requirements. **[Am. 69]**

Devices classified as class D in accordance with the rules set out in Annex VII, ~~even~~ if manufactured and used within a single health institution, shall ~~comply with~~ ***be exempt from*** the requirements of this Regulation. ~~However, the provisions regarding CE marking set out in Article 16 and the obligations~~ ***with the exception of Article 59(4) and general safety performance requirements set out in Annex I where the following conditions are met:***

(a) the recipient patient or patient group's specific needs cannot be met by an available CE-marked device as such, and therefore, either a CE-marked device needs to be modified or a new device needs to be manufactured;

(b) the health institution is accredited with the ISO standard 15189 quality management system, or any other equivalent recognised standard;

(c) the health institution provides the Commission and the competent authority referred to in ~~Articles 21 to 25~~ ***Article 26 with a list of such devices, which*** shall ~~not apply to those~~ ***include a justification of their manufacturing, modification or use. This list shall be regularly updated.***

The Commission shall verify that the devices on that list are eligible for exemption in accordance with the requirements under this paragraph.

The information on exempt devices shall be made public.

Member States shall retain the right to restrict the in-house manufacture and use of any specific type of in-vitro diagnostic device in relation to aspects that are not covered by this Regulation, and may also make the manufacture and use of the devices ***concerned subject to further safety requirements. In such cases, Member States shall inform the Commission and the other Member States accordingly.*** **[Am. 70]**

~~6. The Commission shall be empowered to adopt delegated acts in accordance with Article 85, amending or supplementing, in the light of technical progress and considering the intended users or patients, the general safety and performance requirements set out in Annex I, including the information supplied by the manufacturer.~~ **[Am. 71]**

Article 4a

Genetic information, counselling and informed consent

1. ***A device may only be used for the purpose of a genetic test if an indication is given by persons admitted to the medical profession under the applicable national legislation after a personal consultation.***

2. ***A device may only be used for the purposes of a genetic test if the rights, safety and well-being of the subjects are protected and that the clinical data generated in the course of the genetic testing are going to be reliable and robust.***

3. ***Information. Before using a device for the purpose of a genetic test the person referred to in paragraph 1 shall provide the person concerned with appropriate information on the nature, the significance and the implications of the genetic test.***

4. ***Genetic counselling. Appropriate genetic counselling is mandatory before using a device for the purpose of predictive and prenatal testing and after a genetic condition has been diagnosed. It shall include medical, ethical, social, psychological and legal aspects and shall be provided by physicians or another person qualified under national law in genetic counselling.***

The form and extent of this genetic counselling shall be defined according to the implications of the results of the test and their significance for the person or the members of his or her family.

5. ***Consent. A device may only be used for the purpose of a genetic test after the person concerned has given free and informed consent to it. The consent shall be given explicitly and in writing. It may be revoked at any time in writing or orally.***

6. ***Testing of minors and incapacitated subjects. In the case of minors the informed consent of the parents or legal representative or minors themselves shall be obtained in accordance with national laws; consent shall represent the minor's presumed will and may be revoked at any time, without detriment to the minor. In the case of incapacitated subjects not able to give informed legal consent, the informed consent of the legal representative shall be obtained; consent shall represent the presumed will of the incapacitated subject and may be revoked at any time, without detriment to the person.***

7. ***A device may only be used for the determination of sex in connection with prenatal diagnosis, if the determination fulfils a medical purpose and if there is a risk of serious gender-specific hereditary diseases. By way of derogation from Article 2(1) and (2) this also applies to products which are not intended to fulfil a specific medical purpose.***

8. ***The provisions of this Article on the use of devices for the purpose of genetic tests do not prevent the Member States from maintaining or introducing for reasons of health protection or public order more stringent national legislation in this field.*** **[Am. 271**

Article 5

Distance sales

1. A device offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC to a natural or legal person established in the Union shall comply with this Regulation at the latest when the device is placed on the market.

2. Without prejudice to national legislation regarding the exercise of the medical profession, a device that is not placed on the market but is used in the context of a commercial activity for the provision of a diagnostic or therapeutic service offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC or by other means of communication to a natural or legal person established in the Union shall comply with this Regulation.

2a. ***Service providers providing means of distance communication shall be obliged, upon receiving a request from the competent authority, to disclose the details of entities engaging in distance selling.*** **[Am. 73]**

2b. ***There shall be a prohibition on the marketing, placing in use, distribution, delivery and making available of products whose names, labelling or instructions for use may mislead with regard to the product's characteristics and effects by:***

(a) ***ascribing characteristics, functions and effects to the product which the product does not have;***

(b) ***creating the false impression that treatment or diagnosis using the product is sure to be successful, or failing to inform of a likely risk associated with the use of the product in line with its intended use or for a longer-than-anticipated period;***

(c) ***suggesting uses or characteristics of the product other than those declared when the conformity assessment was carried out.***

Promotional materials, presentations and information about the products may not mislead in the manner referred to in the first subparagraph. **[Am. 74]**

Article 6

Harmonised standards

1. Devices which are in conformity with the relevant harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof.

   The first subparagraph shall also apply to system or process requirements to be fulfilled by economic operators or sponsors in accordance with this Regulation, including those related to the quality management system, risk management, the post-market surveillance plan, clinical performance studies, clinical evidence or post-market follow-up.

2. Reference to harmonised standards also includes the monographs of the European Pharmacopoeia adopted in accordance with the Convention on the Elaboration of a European Pharmacopoeia.

Article 7

Common technical specifications

1. Where no harmonised standards exist or where ~~relevant harmonised standards are not sufficient~~ ***there is a need to address public health concerns***, the Commission, ***after having consulted the MDCG and the MDAC***, shall be empowered to adopt common technical specifications (CTS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annex II or the clinical evidence and post-market follow-up set out in Annex XII. The CTS shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 84(3).

1a. Before adopting CTS as referred to in paragraph 1, the Commission shall ensure that the CTS have been developed with the appropriate support of the relevant stakeholders and that they are coherent with the European and international standardisation system. CTS are coherent if they do not conflict with European standards, meaning they cover areas where no harmonised standards exist, the adoption of new European standards is not envisaged within a reasonable period, where existing standards have not gained market uptake or where those standards have become obsolete or have been demonstrated as clearly insufficient according to vigilance or surveillance data, and where the transposition of the technical specifications into European standardisation deliverables is not envisaged within a reasonable period. **[Am. 75]**

2. Devices which are in conformity with the CTS referred to in paragraph 1 shall be presumed to be in conformity with the requirements of this Regulation covered by those CTS or parts thereof.

3. Manufacturers shall comply with the CTS unless they can duly justify that they have adopted solutions ensuring a level of safety and performance that is at least equivalent thereto.

Article 8

General obligations of the manufacturer

1. When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.

2. Manufacturers shall draw up the technical documentation which shall allow assessment of the conformity of the device with the requirements of this Regulation. The technical documentation shall include the elements set out in Annex II.

~~The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing, in the light of technical progress, the elements in the technical documentation set out in Annex II.~~ **[Am. 76]**

3. Where compliance of a device with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, manufacturers of devices, other than devices for performance evaluation, shall draw up an EU declaration of conformity in accordance with Article 15 and affix the CE marking of conformity in accordance with Article 16.

4. Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any supplement, issued in accordance with Article 43, available to the competent authorities for a period of at least five years after the last device covered by the declaration of conformity has been placed on the market.

   Where the technical documentation is voluminous or held in different locations, the manufacturer shall provide, upon request by a competent authority, a summary technical documentation (STED) and grant access to the full technical documentation upon request.

5. Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation. Changes in product design or characteristics and changes in the harmonised standards or CTS by reference to which conformity of a product is declared shall be adequately taken into account. Proportionate to the risk class and the type of device, manufacturers of devices, other than devices for performance evaluation, shall institute and keep up to date a quality management system that shall address at least the following aspects:

(a) the responsibility of the management;

(b) resource management, including selection and control of suppliers and sub-contractors;

(c) product realisation;

(d) processes for monitoring and measurement of output, data analysis and product improvement.

6. Proportionate to the risk class and the type of device, manufacturers of devices shall institute and keep up to date a systematic procedure to collect and review experience gained from their devices placed on the market or put into service, and to apply any necessary corrective action, hereinafter referred to as 'post-market surveillance plan'. The post-market surveillance plan shall set out the process for collecting, recording***,*** ***communicating to the electronic system on vigilance referred to in Article 60*** and investigating complaints and reports from healthcare professionals, patients or users on suspected incidents related to a device, keeping a register of non-conforming products and product recalls or withdrawals, and if deemed appropriate due to the nature of the device, sample testing of marketed devices. Part of the post-market surveillance plan shall be a plan for post-market follow-up in accordance with Part B of Annex XII. Where post-market follow-up is not deemed necessary, this shall be duly justified and documented in the post-market surveillance plan ***and subject to approval by the competent authority***. **[Am.77]**

If in the course of the post-market surveillance a need for corrective action is identified, the manufacturer shall implement the appropriate measures.

7. Manufacturers shall ensure that ~~the device is accompanied by~~ the information to be supplied ***for the device*** in accordance with Section 17 of Annex I ***is provided*** in an official Union language which can be easily understood by the intended user. The language(s) of the information to be supplied by the manufacturer may be determined by the law of the Member State where the device is made available to the user.

   For devices for self-testing or near-patient-testing, the information supplied in accordance with Section 17 of Annex I shall be ***easily understandable and*** provided in the ***official Union*** language(s) of the Member State where the device reaches its intended user.
   [Ams 78, 79 and 263]

8. Manufacturers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that product into conformity, withdraw it or recall it, as appropriate. They shall inform the ***responsible national competent authority, the*** distributors***, importers*** and, where applicable, the authorised representative accordingly.
   [Am. 80]

9. Manufacturers shall, in response to a reasoned request from a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any corrective action taken to eliminate the risks posed by devices which they have placed on the market or put into service.

If a competent authority considers or has reason to believe that a device has caused damage, it shall ensure, where this is not already provided for by national litigation or judicial proceedings, that the potentially harmed user, the user's successor in title, the user's health insurance company or other third parties affected by the damage caused to the user may request the information referred to in the first subparagraph from the manufacturer or his authorised representative while ensuring due regard for the intellectual property rights. **[Am. 81]**

If facts exist that give reason to assume that an in-vitro medical device has caused damage, the potentially harmed user, his successor in title, his compulsory health insurance or other third parties affected by the damage may also demand the information referred to in the first subparagraph from the manufacturer or his authorised representative.

This right to information shall also exist, subject to the conditions set forth in the first subparagraph , against the competent authorities of the Member States which are responsible for the surveillance of the relevant medical device, as well as against any notified body that issued a certificate pursuant to Article 45 or was otherwise involved in the conformity assessment procedure of the medical device in question. **[Am. 82]**

10. Where manufacturers have their devices designed and manufactured by another legal or natural person, the information on the identity of that person shall be part of the information to be submitted in accordance with Article 23.

10a. Before placing an in vitro diagnostic medical device on the market, manufacturers shall ensure they are covered by appropriate liability insurance covering the risk of insolvency and any damage to patients or users that can be directly attributed to a manufacturing defect of the same medical device, with a level of coverage proportionate to the potential risk associated with the in vitro diagnostic medical device produced, and in accordance with Council Directive 85/374/EEC[1]. **[Am. 83]**

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[1] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ L 210, 7.8.1985, p. 29).

Article 9

Authorised representative

1. A manufacturer of a device that is placed on the Union market, or bears the CE marking without being placed on the Union market, who does not have a registered place of business in a Member State or does not carry out relevant activities at a registered place of business in a Member State, shall designate a single authorised representative.

2. The designation shall be valid only when accepted in writing by the authorised representative and shall be effective at least for all devices of the same generic device group.

3. The authorised representative shall perform the tasks specified in the mandate agreed between the manufacturer and the authorised representative.

   The mandate shall allow and require the authorised representative to perform at least the following tasks in relation to the devices that it covers:

   (a) keep ***available the summary of technical documentation (STED) or on request*** the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any supplement, issued in accordance with Article 43 at the disposal of competent authorities for the period referred to in Article 8(4); **[Am. 84]**

(b) in response to a reasoned request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device;

(c) cooperate with the competent authorities on any corrective action taken to eliminate the risks posed by devices;

(d) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;

(e) terminate the mandate if the manufacturer acts contrary to his obligations under this Regulation.

To allow the authorised representative to fulfil the tasks mentioned in this paragraph, the manufacturer shall at least ensure that the authorised representative has permanent immediate access to the necessary documentation in one of the official Union languages.

4. The mandate referred to in paragraph 3 shall not include the delegation of the manufacturer's obligations laid down in Article 8(1), (2), (5), (6), (7) and (8).

5. An authorised representative who terminates the mandate on the grounds referred to in point (e) of paragraph 3 shall immediately inform the competent authority of the Member State in which he is established and, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefor.

6. Any reference in this Regulation to the competent authority of the Member State where the manufacturer has his registered place of business shall be understood as a reference to the competent authority of the Member State where the authorised representative, designated by a manufacturer referred to in paragraph 1, has his registered place of business.

Article 10

Change of authorised representative

The modalities of a change of authorised representative shall be clearly defined in an agreement between the manufacturer, the outgoing authorised representative and the incoming authorised representative. This agreement shall address at least the following aspects:

(a) the date of termination of the mandate with the outgoing authorised representative and date of beginning of the mandate with the incoming authorised representative;

(b) the date until which the outgoing authorised representative may be indicated in the information supplied by the manufacturer, including any promotional material;

(c) the transfer of documents, including confidentiality aspects and property rights;

(d) the obligation of the outgoing authorised representative after the end of the mandate to forward to the manufacturer or to the incoming authorised representative any complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device for which he had been designated as authorised representative.

Article 11

General obligations of importers

1. Importers shall place on the Union market only devices that are in conformity with this Regulation.

2. Before placing a device on the market importers shall ensure the following:

   (a) that the appropriate conformity assessment procedure has been carried out by the manufacturer;

   (b) that ***a manufacturer is identified and that*** an authorised representative in accordance with Article 9 has been designated by the manufacturer; **[Am. 85]**

   (c) that the EU declaration of conformity and the technical documentation has been drawn up by the manufacturer;

   (d) that the device bears the required CE marking of conformity;

   (e) that the device is labelled in accordance with this Regulation and accompanied by the required instructions for use ~~and EU declaration of conformity~~; **[Am. 86]**

(f) that, where applicable, a Unique Device Identification has been assigned by the manufacturer in accordance with Article 22.

(fa) that the manufacturer has taken out appropriate liability insurance coverage pursuant to Article 8(10a) , unless the importer himself ensures sufficient coverage that meets the requirements of this provision. **[Am. 87]**

Where an importer considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, he shall not place the device on the market until it has been brought into conformity. Where the device presents a risk, the importer shall inform the manufacturer and his authorised representative to that effect, as well as the competent authority of the Member State in which he is established.

3. Importers shall indicate their name, registered trade name or registered trade mark and the address of their registered place of business at which they can be contacted and their location can be established on the device or on its packaging or in a document accompanying the device. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.

4. Importers shall ensure that the device is registered in the electronic system in accordance with Article 23(2).

5. Importers shall ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I.

6. When deemed appropriate with regard to the risks presented by a device, importers shall, in order to protect the health and safety of patients and users, carry out sample testing of marketed products, investigate complaints and keep a register of complaints, of non-conforming products and of product recalls and withdrawals, and shall keep the manufacturer, authorised representative and distributors informed of such monitoring.

7. Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, ***and where applicable*** his authorised representative and, if appropriate, ~~take~~ ***ensure that*** the necessary corrective action to bring that device into conformity, withdraw or recall it ***is taken and, implement that action***. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 43 for the device in question, giving details, in particular, of the non-compliance and of any corrective action ~~taken~~ ***they have implemented***. **[Am. 88]**

8. Importers who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have placed on the market shall immediately forward this information to the manufacturer and his authorised representative.

9. Importers shall, for the period referred to in Article 8(4), keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation and, if applicable, a copy of the relevant certificate including any supplement, issued in accordance with Article 43, can be made available to those authorities, upon request. By written mandate, the importer and the authorised representative for the device in question may agree that this obligation is delegated to the authorised representative.

10. Importers shall, in response to a request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of a product. This obligation shall be considered fulfilled when the authorised representative for the device in question provides the required information. Importers shall cooperate with a competent national authority, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market.

Article 12

General obligations of distributors

1. When making a device available on the market, distributors shall act with due care in relation to the requirements applicable.

2. Before making a device available on the market distributors shall verify that the following requirements are met:

   (a) the product bears the required CE marking of conformity;

   (b) the product is accompanied by the information to be supplied by the manufacturer in accordance with Article 8(7);

   (c) the manufacturer and, where applicable, the importer have complied with the requirements set out in Article 22 and Article 11(3) respectively.

   Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, he shall not make the device available on the market until it has been brought into conformity. Where the device presents a risk, the distributor shall inform the manufacturer and, where applicable, his authorised representative and the importer to that effect, as well as the competent authority of the Member State in which he is established.

3. Distributors shall ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I.

4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer and make sure that***, within the limits of its respective activities,*** the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available, giving details, in particular, of the non-compliance and of any corrective action taken. **[Am. 89]**

5. Distributors who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall immediately forward this information to the manufacturer and, where applicable, his authorised representative.

6. Distributors shall, in response to a request from a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of a device. This obligation shall be considered fulfilled when the authorised representative for the device in question, where applicable, provides the required information. Distributors shall cooperate with competent national authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market.

Article 13

Person responsible for regulatory compliance

1. Manufacturers shall have available within their organisation at least one ~~qualified~~ person ***responsible for regulatory compliance*** who possesses ~~expert knowledge~~ ***the requisite expertise*** in the field of *in vitro* diagnostic medical devices. The ~~expert knowledge~~ ***requisite expertise*** shall be demonstrated by either of the following qualifications:

   (a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in ***law***, natural sciences, medicine, pharmacy, engineering or another relevant discipline~~, and at least two years of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices~~;

(b) ~~five~~ ***three*** years of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices.

2. The ~~qualified~~ person ***responsible for regulatory compliance*** shall at least be responsible for ensuring the following matters:

(a) that the conformity of the devices is appropriately assessed before a batch is released;

(b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;

(c) that the reporting obligations in accordance with Articles 59 to 64 are fulfilled.

(d) in the case of devices for performance evaluation intended to be used in the context of interventional clinical performance studies or other clinical performance studies involving risks for the subjects, that the statement referred to in Section 4.1 of Annex XIII is issued;

If a number of persons are jointly responsible for regulatory compliance in accordance with paragraphs 1 and 2, their respective areas of responsibility shall be stipulated in writing.

3. The ~~qualified~~ person ***responsible for regulatory compliance*** shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties.

4. Authorised representatives shall have available within their organisation at least one ~~qualified~~ person ***responsible for regulatory compliance*** who possesses ~~expert knowledge~~ ***the requisite expertise*** regarding the regulatory requirements for *in vitro* diagnostic medical devices in the Union. The ~~expert knowledge~~ ***requisite expertise*** shall be demonstrated by either of the following qualifications:

   (a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in law, natural sciences, medicine, pharmacy, engineering or another relevant discipline~~, and at least two years of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices~~;

   (b) ~~five~~ ***three*** years of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices. **[Am. 90]**

Article 14

Cases in which obligations of manufacturers apply to importers, distributors or other persons

1. A distributor, importer or other natural or legal person shall assume the obligations incumbent on manufacturers if he does any of the following:

   (a) makes available on the market a device under his name, registered trade name or registered trade mark;

   (b) changes the intended purpose of a device already placed on the market or put into service;

   (c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.

   The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in number (16) of Article 2, assembles or adapts a device already on the market to its intended purpose for an individual patient ***or a specific limited group of patients within a single healthcare institution.*** **[Am. 91]**

2. For the purposes of point (c) of paragraph 1, the following shall not be considered to be a modification of a device that could affect its compliance with the applicable requirements:

(a) provision, including translation, of the information supplied by the manufacturer in accordance with Section 17 of Annex I relating to a device already placed on the market and of further information which is necessary in order to market the product in the relevant Member State;

(b) changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the product in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it. In the case of devices placed on the market in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the package that shall ensure the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.

3. A distributor or importer who carries out any of the activities mentioned in points (a) and (b) of paragraph 2 shall indicate the activity carried out together with his name, registered trade name or registered trade mark and the address at which he can be contacted and his location can be established on the device or, where that is not possible, on its packaging or in a document accompanying the device.

He shall ensure that he has in place a quality management system that includes procedures which ensure that the translation of information is accurate and up-to-date, and that the activities mentioned in points (a) and (b) of paragraph 2 are performed by means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy. Part of the quality management system shall be procedures ensuring that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it in conformity with this Regulation.

4. Prior to making the relabelled or repackaged device available, the distributor or importer referred to in paragraph 3 shall inform the manufacturer and the competent authority of the Member State where he plans to make the device available and, upon request, shall provide them with a sample or a mock-up of the relabelled or repackaged device, including any translated label and instructions for use. He shall submit to the competent authority a certificate, issued by a notified body referred to in Article 27, designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system complies with the requirements laid down in paragraph 3.

4a. Distributors or affiliates who carry out, on behalf of the manufacturer, one or more of the activities mentioned under paragraphs 2(a) and (b) – are exempted from additional requirements under paragraphs 3 and 4. **[Am. 92]**

Article 15

EU declaration of conformity

1. The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated. It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III. It shall be ~~translated into~~ ***issued in one of*** the official Union ~~language or~~ languages ~~required by the Member State(s) in which the device is made available~~. **[Am. 264]**

2. Where, concerning aspects not covered by this Regulation, devices are subject to other Union legislation which also requires a declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated, a single EU declaration of conformity shall be drawn up in respect of all Union acts applicable to the device containing all information required for identification of the Union legislation to which the declaration relates.

3. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for compliance with the requirements of this Regulation and all other Union legislation applicable to the device.

~~4. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the minimum content of the EU declaration of conformity set out in Annex III in the light of technical progress.~~ **[Am. 93]**

Article 16

CE marking of conformity

1. Devices, other than devices for performance evaluation, considered to be in conformity with the requirements of this Regulation shall bear the CE marking of conformity, as presented in Annex IV.

2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

3. The CE marking shall be affixed visibly, legibly and indelibly to the device or its sterile pack. Where that is not possible or not warranted on account of the nature of the device, it shall be affixed to the packaging. The CE marking shall also appear in the instructions for use and on the sales packaging where those are provided.

4. The CE marking shall be affixed before the device is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.

5. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 40. The identification number shall also be indicated in any promotional material which mentions that a device fulfils the legal requirements for CE marking.

6. Where devices are subject to other Union legislation concerning other aspects which also provide for the affixing of the CE marking, the CE marking shall indicate that the devices also fulfil the provisions of the other legislation.

Article 17

Devices for special purposes

1. Member States shall not create any obstacle to devices for performance evaluation which are supplied for that purpose to laboratories or other institutions, if they meet the conditions laid down in Articles 48 to 58.

2. Those devices shall not bear the CE marking, with the exception of the devices referred to in Article 52.

3. At trade fairs, exhibitions, demonstrations or similar events, Member States shall not create any obstacle to the showing of devices which do not comply with this Regulation, provided such devices are not used on specimens taken from the participants and a visible sign clearly indicates that such devices are intended for presentation or demonstration purposes only and cannot be made available until they have been made to comply with this Regulation.

Article 18

Systems and procedure packs

1. Any natural or legal person shall draw up a statement referred to in paragraph 2 if he puts devices bearing the CE marking together with the following other devices or products, in accordance with the intended purpose of the devices or other products and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack:

   – other devices bearing the CE marking;

   – medical devices bearing the CE marking in conformity with Regulation (EU) .../... [Ref. of future Regulation on medical devices];

   – other products which are in conformity with the legislation applicable to those products.

2. In the statement, the person referred to in paragraph 1 shall declare the following:

   (a) that he verified the mutual compatibility of the devices and, if applicable other products, in accordance with the manufacturers' instructions and has carried out his operations in accordance with those instructions;

(b) that he packaged the system or procedure pack and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together;

(c) that the activity of putting devices and, if applicable, other products together as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.

3. Any natural or legal person who sterilises systems or procedure packs referred to in paragraph 1 for the purpose of placing them on the market shall, at his choice, follow one of the procedures referred to in Annex VIII or in Annex X. The application of those Annexes and the involvement of the notified body shall be limited to the aspects of the procedure relating to ensuring sterility until the sterile package is opened or damaged. The person shall draw up a statement declaring that the sterilisation has been carried out in accordance with the manufacturer's instructions.

4. Where the system or procedure pack incorporate devices which do not bear the CE marking or where the chosen combination of devices is not compatible in view of their original intended purpose, the system or procedure pack shall be treated as a device in its own right and shall be subjected to the relevant conformity assessment procedure pursuant to Article 40.

5. The systems or procedure packs referred to in paragraph 1 shall not themselves bear an additional CE marking but they shall bear the name, registered trade name or registered trade mark of the person referred to in paragraph 1 as well as the address at which he can be contacted and his location can be established. Systems or procedure packs shall be accompanied by the information referred to in Section 17 of Annex I. The statement referred to in paragraph 2 of this Article shall be kept at the disposal of the competent authorities, after the system or procedure pack has been put together, for the period that is applicable to the devices put together in accordance with Article 8(4). Where these periods differ, the longest period shall apply.

Article 19

Parts and components

1. Any natural or legal person who makes available on the market an article intended specifically to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or re-establish the function of the device, without ~~significantly~~ changing its performance or safety characteristics, shall ensure that the article does not adversely affect the safety and performance of the device. Substantiating evidence shall be kept available to the competent authorities of the Member States. **[Am. 94]**

2. An article that is intended specifically to replace a part or component of a device and that ~~significantly~~ changes the performance or safety characteristics of the device shall be considered ***as a*** device ***and shall meet the requirements laid down in this Regulation.*** **[Am. 95]**

Article 20

Free movement

Member States shall not refuse, prohibit or restrict the making available or putting into service within their territory of devices which comply with the requirements of this Regulation.

Chapter ~~III~~*VII*

Identification and traceability of devices, registration of devices and of economic operators, summary of safety and performance, European databank on medical devices [Am. 101]

Article 21

Identification within the supply chain

For devices, other than devices for performance evaluation, economic operators shall be able to identify the following, for the period referred to in Article 8(4):

(a) any economic operator to whom they have supplied a device;

(b) any economic operator who has supplied them with a device;

(c) any health institution or healthcare professional to whom they have supplied a device.

Upon request, they shall inform the competent authorities thereof.

Article 22

Unique device identification system

1. For devices, other than devices for performance evaluation, a system for Unique Device Identification shall be put in place in the Union. The UDI system shall allow the identification and traceability of devices and shall consist of the following:

   (a) production of a UDI that comprises the following:

      (i) a device identifier specific to a manufacturer and a device model, providing access to the information laid down in Part B of Annex V;

      (ii) a production identifier that identifies data related to the unit of device production.

   (b) placement of the UDI on the label of the device;

   (c) storage of the UDI by the economic operators and the health institutions through electronic means;

   (d) establishment of an electronic system on UDI.

2. The Commission shall designate one or several entities that operate a system for assignment of UDIs pursuant to this Regulation and that satisfy all of the following criteria:

(a) the entity is an organisation with legal personality;

(b) its system for the assignment of UDIs is adequate to identify a device through its distribution and use in accordance with the requirements of this Regulation;

(c) its system for the assignment of UDIs conforms to the relevant international standards;

(d) the entity gives access to its system for the assignment of UDIs to all interested users according to a set of predetermined and transparent terms and conditions;

(e) the entity undertakes the following:

(i) to operate its system for the assignment of UDIs for the period to be determined in the designation which shall at least be ~~three~~ ***five*** years after its designation; **[Am. 96]**

(ii) to make available to the Commission and to the Member States, upon request, information concerning its system for the assignment of UDIs and concerning manufacturers that place an UDI on the label of their device in accordance with the entity's system;

(iii) to remain in compliance with the criteria for designation and the terms of designation during the period for which it is designated.

3. Before placing a device on the market, the manufacturer shall assign to the device a UDI provided by an entity designated by the Commission in accordance with paragraph 2, if that device belongs to the devices, categories or groups of devices determined by a measure referred to in point (a) of paragraph 7.

4. The UDI shall be placed on the label of the device, in accordance with the conditions laid down by a measure referred to in point (c) of paragraph 7. It shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 59. The device identifier shall appear on the EU declaration of conformity referred to in Article 15 and in the technical documentation referred to in Annex II.

5. Economic operators and health institutions shall store and keep, by electronic means, the device identifier and the production identifier of the devices which they have supplied or they have been supplied with, if they belong to the devices, categories or groups of devices determined by a measure referred to in point (a) of paragraph 7.

6. The Commission, in cooperation with the Member States, shall set up and manage an electronic system on UDI to collate and process the information mentioned in Part B of Annex V. This information shall be accessible to the public.

7. The Commission shall be empowered to adopt delegated acts in accordance with Article 85:

   (a) determining the devices, categories or groups of devices, whose identification shall be based on the UDI system, as set out in paragraphs 1 to 6, and the timelines for implementing this. Following a risk-based approach, implementation of the UDI system shall be gradual, starting with devices falling in the highest risk class;

   (b) specifying the data to be included in the production identifier which, following a risk-based approach, may vary depending on the risk class of the device;

(c) defining the obligations of economic operators, of health institutions and of professional users, in particular regarding allocation of the numeric or alphanumeric characters, placement of the UDI on the label, storage of information in the electronic system on UDI, and use of the UDI in documentation and reporting related to the device provided for in this Regulation;

(d) amending or supplementing the list of information set out in Part B of Annex V in the light of technical progress.

8. When adopting the measures referred to in paragraph 7, the Commission shall take into account the following:

(a) the protection of personal data;

(b) the legitimate interest in protecting commercially sensitive information***, to the extent that it does not undermine public health protection***; **[Am. 97]**

(c) the risk-based approach;

(d) the cost-effectiveness of the measures;

(e) the convergence of UDI systems developed at international level.

(ea) compatibility with medical device identification systems already on the market. **[Am. 98]**

(eb) compatibility with the other traceability systems used by medical device stakeholders. **[Am. 99]**

Article 23

Electronic system on registration of devices and economic operators

1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information that is necessary and proportionate to describe and identify the device and to identify the manufacturer and, where applicable, the authorised representative and the importer***, and to ensure transparency and safe and effective use by making available to users current evidence concerning the clinical validity and, where applicable, utility of the device***. The details regarding the information to be submitted by the economic operators are laid down in Part A of Annex V. **[Am. 100]**

2. Before a device, other than a device for performance evaluation, is placed on the market the manufacturer or his authorised representative shall submit to the electronic system the information referred to in paragraph 1.

3. Within one week after placing a device, other than a device for performance evaluation, on the market, importers shall submit to the electronic system the information referred to in paragraph 1.

4. Within one week of any change occurring in relation to the information referred to in paragraph 1, the relevant economic operator shall update the data in the electronic system.

5. Not later than two years after submission of the information in accordance with paragraphs 2 and 3, and then every second year, the relevant economic operator shall confirm the accuracy of the data. In the event of failure to confirm within six months of the due date, any Member State may take measures to suspend or otherwise restrict the making available of the device in question within its territory until the obligation referred to in this paragraph is complied with.

6. The data contained in the electronic system shall be accessible to the public.

7. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending the list of information to be submitted as set out in Part A of Annex V in the light of technical progress.

Article 24

~~Summary of safety~~ ***Safety*** *and* ***clinical*** *performance* ***report***

1. In the case of devices classified as class C and D, other than devices for performance evaluation, the manufacturer shall draw up a ~~summary of~~ ***report on the*** safety and ***clinical*** performance~~.~~ ~~It~~ ***of the device based on the full information collected during the clinical performance study. The manufacturer shall also draw up a summary of that report which*** shall be written in a way that is ~~clear to the intended user~~***easy for a lay person to understand in the official language(s) of the country where the device is made available on the market***. The draft ~~of this summary~~ ***report*** shall be part of the documentation to be submitted to ***and validated by*** the notified body, ***and where relevant by the special notified body***, involved in the conformity assessment in accordance with ~~Article~~ ***Articles*** 40 ***and 43a*** ~~and shall be validated by that body~~.

1a. ***The summary referred to in paragraph 1 shall be made available to the public through Eudamed in accordance with point (b) of the second paragraph of Article 25 and point 15 of Annex V, Part A.***

2. The Commission may, by means of implementing acts, set out the ~~form and~~ ***format of*** the presentation of the data elements to be included in ***both the report and*** the summary ~~of safety and performance~~ ***referred to in paragraph 1***. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 84(2). **[Am. 102]**

Article 25

European databank

The Commission shall develop and manage the European databank on medical devices (Eudamed) in accordance with the conditions and modalities established by Article 27 of Regulation (EU) [Ref. of future Regulation on medical devices].

Eudamed shall include the following as integral parts:

(a) the electronic system on UDI referred to in Article 22;

(b) the electronic system on registration of devices and economic operators referred to in Article 23;

(c) the electronic system on information on certificates referred to in Article 43(4);

(d) the electronic system on interventional clinical performance studies and clinical performance studies involving risks for the subjects set up in Article 51;

(e) the electronic system on vigilance referred to in Article 60;

(f) the electronic system on market surveillance referred to in Article 66.

(fa) the electronic system on registration of subsidiaries and subcontracting referred to in Article 28a.

(fb) the electronic system on "special notified bodies" referred to in Article 41b.

[Am. 103]

Chapter ~~VII~~*VIII*

Vigilance and market surveillance [Am. 179]

SECTION 1 — VIGILANCE

Article 59

Reporting of incidents and field safety corrective actions

1. Manufacturers of devices, other than devices for performance evaluation, shall report through the electronic system referred to in Article 60 the following:

   (a) any ~~serious~~ incident, ***including the date and place of the incident, with an indication of whether it is serious in accordance with the definition under Article 2,*** in respect of devices made available on the Union market; ***where available, the manufacturer shall include information on the patient or user and healthcare professional involved in the incident***;

   (b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market if the reason for the field safety corrective action is not limited to the device made available in the third country.

Manufacturers shall make the report referred to in the first subparagraph without delay, and no later than 15 days after they have become aware of the event and the causal relationship with their device or that such causal relationship is reasonably possible. The time period for reporting shall take account of the severity of the incident. Where necessary to ensure timely reporting, the manufacturer may submit an initial incomplete report followed up by a complete report.

2. For similar ~~serious~~ incidents occurring with the same device or device type and for which the root cause has been identified or the field safety corrective action implemented, manufacturers may provide periodic summary reports instead of individual incident reports, on condition that the competent authorities referred to in points (a), (b) and (c) of Article 60(5) have agreed with the manufacturer on the format, content and frequency of the periodic summary reporting.

3. The Member States shall take all appropriate measures, ***including targeted information campaigns***, to encourage ***and enable*** healthcare professionals, ***including doctors and pharmacists***, users and patients to report to their competent authorities suspected ~~serious~~ incidents referred to in point (a) of paragraph 1. They ***shall inform the Commission of those measures.***

~~They~~ ***The competent authorities of the Member States*** shall record such reports centrally at national level. Where a competent authority of a Member State obtains such reports, it shall ~~take the necessary steps to ensure that~~ ***inform*** the manufacturer of the device concerned ~~is informed of the incident~~ ***without delay***. The manufacturer shall ensure the appropriate follow-up.

The competent authority of a Member State shall notify the reports referred to in the first subparagraph to the electronic system referred to in Article 60 without delay, unless the same incident has already been reported by the manufacturer.

The ***Commission, in cooperation with the*** Member States ***and in consultation with the relevant stakeholders,*** shall ~~coordinate between them the development of~~ ***develop*** standard ~~web-based structured~~ forms for ***electronic and non-electronic*** reporting of ~~serious~~ incidents by healthcare professionals, users and patients.

4. Health institutions manufacturing and using devices referred to in Article 4(4) shall ***immediately*** report any ~~serious~~ incidents and field safety corrective actions referred to in paragraph 1 to the competent authority of the Member State in which the health institution is located. **[Am. 180]**

Article 60

Electronic system on vigilance

1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system to collate and process the following information:

   (a) the reports by manufacturers on ~~serious~~ incidents and field safety corrective actions referred to in Article 59(1);

   (b) the periodic summary reports by manufacturers referred to in Article 59(2);

   (c) the reports by competent authorities on ~~serious~~ incidents referred to in the second subparagraph of Article 61(1);

   (d) the reports by manufacturers on trends referred to in Article 62;

   (e) the field safety notices by manufacturers referred to in Article 61(4);

   (f) the information to be exchanged between the competent authorities of the Member States and between them and the Commission in accordance with Article 61(3) and (6).

(fa) the reports by competent authorities on serious incidents and field safety corrective actions taken within health institutions involving devices referred to in Article 4(4)

2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission, to the notified bodies, ***to healthcare professionals and also to manufacturers where the information pertains to their own product***.

3. The Commission shall ensure that ~~healthcare professionals and~~ the public ~~have~~ ***has an*** appropriate ~~levels~~ ***level*** of access to the electronic system. ***Where information is requested on a specific in vitro diagnostic medical device, that information shall be made available without delay and within 15 days at the latest.***

4. On the basis of arrangements between the Commission and competent authorities of third countries or international organisations, the Commission may grant those competent authorities or international organisations access to the database at the appropriate level. Those arrangements shall be based on reciprocity and make provision for confidentiality and data protection equivalent to those applicable in the Union.

5. The reports on ~~serious~~ incidents and field safety corrective actions referred to in points (a) and (b) of Article 59(1), the periodic summary reports referred to in Article 59(2), the reports on ~~serious~~ incidents referred to in the second subparagraph of Article 61(1) and the trend reports referred to in Article 62 shall be automatically transmitted upon receipt via the electronic system to the competent authorities of the following Member States

(a) the Member State where the incident occurred;

(b) the Member State where the field safety corrective action is being or is to be undertaken;

(c) the Member State where the manufacturer has his registered place of business;

(d) where applicable, the Member State where the notified body, that issued a certificate in accordance with Article 43 for the device in question, is established.

5a. The reports and information referred to in Article 60(5), shall also be automatically transmitted for the device in question via the electronic system to the notified body that issued the certificate in accordance with Article 43. **[Am. 181]**

Article 61

Analysis of serious incidents and field safety corrective action

1. Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 59 is, at national level, evaluated centrally by their competent authority, if possible together with the manufacturer. ***The competent authority shall take into account the views of all relevant stakeholders, including patient and healthcare professionals' organisations and manufacturers' associations.*** **[Am. 182]**

~~If in the case of reports received in accordance with Article 59(3) the competent authority ascertains that the reports relate to a serious incident it shall notify without delay those reports to the electronic system referred to in Article 60, unless the same incident has already been reported by the manufacturer.~~ **[Am. 183]**

2. The national competent authorities shall carry out a risk assessment with regard to reported serious incidents or field safety corrective actions, taking into account criteria such as causality, detectability and probability of recurrence of the problem, frequency of use of the device, probability of occurrence of harm and severity of harm, clinical benefit of the device, intended and potential users, and population affected. They shall also evaluate the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for and kind of any other corrective action. They shall monitor the manufacturer's investigation of the ***serious*** incident. **[Am. 184]**

3. After carrying out the assessment, the evaluating competent authority shall, through the electronic system referred to in Article 60, inform without delay the other competent authorities of the corrective action taken or envisaged by the manufacturer or imposed on him to minimise the risk of recurrence of a serious incident, including information on the underlying events and the outcome of its assessment.

4. The manufacturer shall ensure that the users of the device in question are informed without delay of the corrective action taken by means of a field safety notice. Except in case of urgency, the content of the draft field safety notice shall be submitted to the evaluating competent authority or, in cases referred to in paragraph 5 of this Article, the coordinating competent authority to allow them to make comments. Unless duly justified by the situation of the individual Member State, the content of the field safety notice shall be consistent in all Member States.

   The manufacturer shall enter the field safety notice in the electronic system referred to in Article 60 through which that notice shall be accessible to the public.

5. The competent authorities shall designate a coordinating competent authority to coordinate their assessments referred to in paragraph 2 in the following cases:

   (a) where similar serious incidents related to the same device or type of device of the same manufacturer occur in more than one Member State;

   (b) where the field safety corrective action is being or is to be undertaken in more than one Member State.

Unless otherwise agreed between the competent authorities, the coordinating competent authority shall be the one of the Member State where the manufacturer has his registered place of business.

The coordinating competent authority shall inform the manufacturer, the other competent authorities and the Commission that it has assumed the role of coordinating authority.

6. The coordinating competent authority shall carry out the following tasks:

(a) to monitor the investigation of the serious incident by the manufacturer and the corrective action to be taken;

(b) to consult with the notified body that issued a certificate in accordance with Article 43 for the device in question regarding the impact of the serious incident on the certificate;

(c) to agree with the manufacturer and the other competent authorities referred to in points (a) to (c) of Article 60(5) on the format, content and frequency of periodic summary reports in accordance with Article 59(2);

(d) to agree with the manufacturer and other competent authorities concerned on the implementation of the appropriate field safety corrective action;

(e) to inform the other competent authorities and the Commission, through the electronic system referred to in Article 60, of the progress in and the outcome of its assessment.

The designation of a coordinating competent authority shall not affect the rights of the other competent authorities to perform their own assessment and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating competent authority and the Commission shall be kept informed of the outcome of any such assessment and the adoption of any such measures.

7. The Commission shall provide secretarial support to the coordinating competent authority in the accomplishment of its tasks under this Chapter.

Article 62

Trend reporting

Manufacturers of devices classified in class C or D shall report to the electronic system referred to in Article 60 any statistically significant increase in the frequency or severity of incidents that are not serious incidents or of expected undesirable effects that have a significant impact on the risk-benefit analysis referred to in Sections 1 and 5 of Annex I and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons when weighted against the intended benefits. The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents or expected undesirable effects in respect of the device, or category or group of devices, in question during a specific time period as established in the manufacturer's conformity assessment. Article 61 shall apply.

Article 63

Documentation of vigilance data

Manufacturers shall update their technical documentation with information on incidents received from healthcare professionals, patients and users, serious incidents, field safety corrective actions, periodic summary reports referred to in Article 59, trend reports referred to in Article 62 and field safety notices referred to in Article 61(4). They shall make this documentation available to their notified bodies, which shall assess the impact of the vigilance data on the conformity assessment and the certificate issued.

Article 64

Implementing acts

The Commission may, by means of implementing acts, adopt the modalities and procedural aspects necessary for the implementation of Articles 59 to 63 as regards the following:

(a) typology of serious incidents and field safety corrective actions in relation to specific devices, or categories or groups of devices;

(b) harmonised forms for the reporting of serious incidents and field safety corrective actions, periodic summary reports and trend reports by manufacturers as referred to in Articles 59 and 62;

(c) timelines for the reporting of serious incidents and field safety corrective actions, periodic summary reports and trend reports by manufacturers, taking into account the severity of the event to be reported as referred to in Articles 59 and 62;

(d) harmonised forms for the exchange of information between competent authorities as referred to in Article 61.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

SECTION 2 — MARKET SURVEILLANCE

Article 65

Market surveillance activities

1. The competent authorities shall perform appropriate checks on the characteristics and performance of devices including, where appropriate, review of documentation and physical or laboratory checks on the basis of adequate samples. They shall take account of established principles regarding risk assessment and risk management, vigilance data and complaints. The competent authorities may require economic operators to make available the documentation and information necessary for the purpose of carrying out their activities, and~~, where necessary and justified,~~ enter ***and inspect*** the premises of economic operators and take the necessary samples of devices ***for analysis by an official laboratory***. They may destroy or otherwise render inoperable devices presenting a ~~serious~~ risk where they deem it necessary.

1a. ***The competent authorities shall designate inspectors who shall be empowered to carry out the checks referred to in paragraph 1. The checks shall be carried out by the inspectors of the Member State in which the economic operator is located. Those inspectors may be assisted by experts appointed by the competent authorities.***

1b. ***Unannounced inspections may also be carried out. The organisation and implementation of such inspections shall always take account of the principle of proportionality, particularly with reference to the hazard potential of a particular product.***

1c. ***Following each inspection carried out under paragraph 1, the competent authority shall draw up a report on compliance by the economic operator inspected with the legal and technical requirements applicable under this Regulation and any corrective actions needed.***

1d. ***The competent authority which carried out the inspection shall communicate the content of this report to the inspected economic operator. Before adopting the report, the competent authority shall give the inspected economic operator the opportunity to submit comments. The final inspection report as referred to in paragraph 1b shall be entered into the electronic system provided for in Article 66.***

1e. ***Without prejudice to any international agreements concluded between the Union and third countries, checks as referred to in paragraph 1 can also take place in the premises of an economic operator located in a third country, if the device is intended to be made available on the Union market.***

2. The Member States shall ***draw up strategic surveillance plans covering their planned surveillance activities, as well as the human and material resources needed to carry those activities out***. ***Member States shall*** periodically review and assess the ~~functioning~~ ***implementation*** of their surveillance ~~activities~~ ***plans***. Such reviews and assessments shall be carried out at least every ~~four~~ ***two*** years and the results thereof shall be communicated to the other Member States and the Commission. ***The Commission may make recommendations for adjustments to the surveillance plans.*** The Member ~~State concerned~~ ***States*** shall make a summary of the results ***and of the Commission's recommendations*** accessible to the public. **[Am. 185]**

3. The competent authorities of the Member States shall coordinate their market surveillance activities, cooperate with each other and share with each other and with the Commission the results thereof. Where appropriate, the competent authorities of the Member States shall agree on work-sharing and specialisation.

4. Where more than one authority in a Member State is responsible for market surveillance and external border controls, those authorities shall cooperate with each other, by sharing information relevant to their role and functions.

5. The competent authorities of the Member States shall cooperate with the competent authorities of third countries with a view to exchanging information and technical support and promoting activities relating to market surveillance.

Article 66

Electronic system on market surveillance

1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process the following information:

(a) information in relation to non-compliant devices presenting a risk to health and safety referred to in Article 68(2), (4) and (6);

(b) information in relation to compliant devices presenting a risk to health and safety referred to in Article 70(2);

(c) information in relation to formal non-compliance of products referred to in Article 71(2);

(d) information in relation to preventive health protection measures referred to in Article 72(2).

2. The information mentioned in paragraph 1 shall be immediately transmitted through the electronic system to all competent authorities concerned and be accessible to the Member States***, to the Commission, to the Agency*** and to ***healthcare professionals. The Commission shall also ensure that the public has an appropriate level of access to the electronic system. In particular, it shall ensure that, where information is requested on a specific in vitro diagnostic medical device, it is made available without delay and within 15 days. The Commission, in consultation with the Medical Devices Coordination Group, shall provide an overview of this information, every six months, for the public and healthcare professionals. This information shall be accessible through the European databank referred to in Article 25.*** **[Am. 186]**

Article 67

Evaluation regarding devices presenting a risk to health and safety at national level

Where the competent authorities of a Member State, based on vigilance data or other information, have sufficient reason to believe that a device presents a risk to the health or safety of patients, users or other persons, they shall carry out an evaluation in relation to the device concerned covering all the requirements laid down in this Regulation that are relevant to the risk presented by the device. The relevant economic operators shall cooperate as necessary with the competent authorities.

Article 68

Procedure for dealing with non-compliant devices presenting a risk to health and safety

1. Where, having performed an evaluation pursuant to Article 67, the competent authorities find that the device, which presents a risk to the health or safety of patients, users or other persons, does not comply with the requirements laid down in this Regulation, they shall without delay require the relevant economic operator to take all appropriate and duly justified corrective action to bring the device into compliance with those requirements, to prohibit or restrict the making available of the device on the market, to subject the making available of the device to specific requirements, to withdraw the device from the market, or to recall it within a reasonable period, proportionate to the nature of the risk.

2. Where the competent authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operators to take, by means of the electronic system referred to in Article 66.

3. The economic operators shall ensure that all appropriate corrective action is taken in respect of all the devices concerned that they have made available on the market throughout the Union.

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in paragraph 1, the competent authorities shall take all appropriate provisional measures to prohibit or restrict the device's being made available on their national market, to withdraw the device from that market or to recall it.

   They shall notify the Commission and the other Member States, without delay, of those measures, by means of the electronic system referred to in Article 66.

5. The notification referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant device, the origin of the device, the nature of and the reasons for the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator.

6. Member States other than the Member State initiating the procedure shall without delay inform the Commission and the other Member States of any additional information at their disposal relating to the non-compliance of the device concerned and of any measures adopted by them in relation to the device concerned. In the event of disagreement with the notified national measure, they shall without delay inform the Commission and the other Member States of their objections, by means of the electronic system referred to in Article 66.

7. Where, within two months of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

8. All Member States shall ensure that appropriate restrictive measures are taken without delay in respect of the device concerned.

Article 69

Procedure at Union level

1. Where, within two months of receipt of the notification referred to in Article 68(4), objections are raised by a Member State against a provisional measure taken by another Member State, or where the Commission considers the measure to be contrary to Union legislation, the Commission shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide, by means of implementing acts, whether or not the national measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

2. If the national measure is considered justified, Article 68(8) shall apply. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure. Where, in the situations referred to in Articles 68 and 70, a Member State or the Commission consider that the risk to health and safety emanating from a device cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, the Commission, at the request of a Member State or on its own initiative, may take, by means of implementing acts, the necessary and duly justified measures to ensure the protection of health and safety, including measures restricting or prohibiting the placing on the market and putting into service of the device concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

3. On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts referred to in paragraphs 1 and 2 in accordance with the procedure referred to in Article 84(4).

Article 70

Procedure for dealing with compliant devices presenting a risk to health and safety

1. Where, having performed an evaluation pursuant to Article 67, a Member State finds that although a device has been legally placed on the market or put into service, it presents a risk to the health or safety of patients, users or other persons or to other aspects of the protection of public health, it shall require the relevant economic operator or operators to take all appropriate provisional measures to ensure that the device concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the device from the market or to recall it within a reasonable period, proportionate to the nature of the risk.

2. The Member State shall immediately notify the Commission and the other Member States of the measures taken, by means of the electronic system referred to in Article 66. That information shall include the data necessary for the identification of the device concerned, the origin and the supply chain of the device, the findings of the Member State's evaluation specifying the nature of the risk involved and the nature and duration of the national measures taken.

3. The Commission shall evaluate the provisional national measures taken. On the basis of the results of that evaluation, the Commission shall decide, by means of implementing acts, whether or not the measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3). On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 84(4).

4. Where the national measure is considered justified, Article 68(8) shall apply. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.

Article 71

Formal non-compliance

1. Without prejudice to Article 68, a Member State shall require the relevant economic operator to put an end to the non-compliance concerned within a reasonable period that is proportionate to the non-compliance where it makes one of the following findings:

(a) that the CE marking has been affixed in violation of the formal requirements laid down in Article 16;

(b) that the CE marking has not been affixed to a device contrary to Article 16;

(c) that the CE marking has been inappropriately affixed in accordance with procedures in this Regulation on a product that is not covered by this Regulation;

(d) that the EU declaration of conformity has not been drawn up or is not complete;

(e) that the information to be supplied by the manufacturer on the label or in the instructions for use is not available, not complete, or not provided in the language(s) required;

(f) that the technical documentation, including the clinical evaluation, is not available or not complete.

2. Where the economic operator does not put an end to the non-compliance within the period referred to in paragraph 1, the Member State concerned shall take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the market. That Member State shall inform the Commission and the other Member States without delay of those measures, by means of the electronic system referred to in Article 66.

Article 72

Preventive health protection measures

1. Where a Member State, after having performed an evaluation which indicates a potential risk related to a device or a specific category or group of devices considers that the making available on the market or putting into service of such device or specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or, category or group of devices should be withdrawn from the market or recalled in order to protect the health and safety of patients, users or other persons or other aspects of public health, it may take any necessary and justified provisional measures.

2. The Member State shall immediately notify the Commission and all other Member States, giving the reasons for its decision, by means of the electronic system referred to in Article 66.

3. The Commission shall assess the provisional national measures taken. The Commission shall decide, by means of implementing acts, whether the national measures are justified or not. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

   On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission may adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 84(4).

4. Where the assessment referred to in paragraph 3 demonstrates that the making available on the market or putting into service of a device, specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled in all Member States in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 to take the necessary and duly justified measures.

   Where in this case imperative grounds of urgency so require, the procedure provided for in Article 86 shall apply to delegated acts adopted pursuant to this paragraph.

Article 73

Good administrative practice

1. Any measure adopted by the competent authorities of the Member States pursuant to Articles 68 to 72 shall state the exact grounds on which it is based. Where it is addressed to a specific economic operator, it shall be notified without delay to the economic operator concerned, who shall at the same time be informed of the remedies available to him under the law of the Member State concerned and of the time limits to which such remedies are subject. Where the measure is of general scope, it shall be appropriately published.

2. Except in cases where immediate action is necessary for reasons of serious risk to human health or safety, the economic operator concerned shall be given the opportunity to make submissions to the competent authority within an appropriate period of time before any measure is adopted. If action has been taken without the economic operator's being heard, he shall be given the opportunity to make submissions as soon as possible and the action taken shall be reviewed promptly thereafter.

3. Any measure adopted shall be immediately withdrawn or amended upon the economic operator's demonstrating that he has taken effective corrective action.

4. Where a measure adopted pursuant to Articles 68 to 72 concerns a product for which a notified body has been involved in the conformity assessment, the competent authorities shall inform the relevant notified body of the measure taken.

Chapter ~~VIII~~*IX*

Cooperation between Member States, Medical Device Coordination Group, *Medical Device Advisory Committee,* EU reference laboratories, device registers [Am. 187]

Article 74

Competent authorities

1. The Member States shall designate the competent authority or authorities responsible for the implementation of this Regulation. They shall entrust their authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this Regulation. The Member States shall communicate the competent authorities to the Commission which shall publish a list of competent authorities.

2. For the implementation of Articles 48 to 58, the Member States may designate a national contact point other than a national authority. In this case, references to a competent authority in this Regulation shall be understood as including the national contact point.

Article 75

Cooperation

1. The competent authorities of the Member States shall cooperate with each other and with the Commission and exchange with each other the information necessary to enable this Regulation to be applied uniformly.

2. Member States and the Commission shall participate in initiatives developed at international level with the aim of ensuring cooperation between regulatory authorities in the field of medical devices.

Article 76

Medical Device Coordination Group

The Medical Device Coordination Group (MDCG) established in accordance with the conditions and modalities defined in Article 78 of Regulation (EU) .../... [Ref. of future Regulation on medical devices] shall carry out, with the support of the Commission as provided in Article 79 of that Regulation, the tasks assigned to it by this Regulation.

Article 76a

Medical Device Advisory Committee

The Medical Device Advisory Committee (MDAC) established in accordance with the conditions and modalities defined in Article 78a of Regulation (EU) No ...[*] shall carry out, with the support of the Commission the tasks assigned to it by this Regulation. **[Am. 188]**

Article 76b

Assessment Committee for Medical Devices

1. ***An Assessment Committee for Medical Devices (ACMD) is hereby established, under the principles of highest scientific competence, impartiality, transparency and to avoid potential conflicts of interest.***

2. ***When undertaking a clinical assessment for a specific device, the ACMD shall be composed of:***

- ***a minimum of five clinical experts in the field of which a clinical assessment and recommendation have been requested;***
- ***one representative of the EMA;***

[*] ***The reference and date etc.***

- ***one representative of the Commission;***

- ***one representative of patients' organisations appointed by the Commission in a transparent manner after a call for interest, for a three-year term which may be renewed.***

The ACMD shall meet on request from the MDCG and Commission, and its meetings shall be chaired by a Commission representative.

The Commission shall ensure that the composition of the ACMD corresponds to the expertise needed for the purpose of its clinical assessment and recommendation.

The Commission shall be responsible for providing the secretariat of this Committee.

3. ***The Commission shall establish a pool of clinical experts in the medical fields relevant to in vitro diagnostic medical devices being assessed by the ACMD.***

In order to undertake the clinical assessment and recommendation procedure, each Member State may propose one expert, following a Union-wide call for expression of interest with a clear definition by the Commission of the requested profile. The publication of the call shall be widely advertised. Each expert shall be approved by the Commission and listed for a three-year term which may be renewed.

The Members of the ACMD shall be chosen for their competence and experience in the corresponding field. They shall perform their tasks with impartiality and objectivity. They shall be completely independent and shall neither seek nor take instructions from any government, notified body or manufacturer. Each member shall draw up a declaration of interests which shall be made publicly available.

In the light of technical progress and any information which becomes available, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the fields referred to in the first subparagraph of this paragraph.

4. ***The ACMD shall fulfil the tasks defined in Article 44a. When adopting its clinical assessment and recommendation, the members of the ACMD shall use their best endeavours to reach consensus. If consensus cannot be reached, the ACMD shall decide by the majority of its members. Any diverging opinion shall be annexed to the ACMD opinion.***

5. The ACMD shall establish its rules of procedure which shall, in particular, lay down procedures for the following:

- ***the adoption of opinions, including in case of urgency;***
- ***the delegation of tasks to reporting and co-reporting members.*** **[Am. 260]**

Article 77

Tasks of the MDCG

The MDCG shall have the following tasks:

(-a) to provide regulatory opinions on the basis of a scientific assessment on certain types of in vitro diagnostic medical devices pursuant to Article 44a;

(a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;

(aa) to establish and document the high level principles of competence and qualification and procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing). The qualification criteria shall address the various functions within the conformity assessment process as well as the devices, technologies and areas covered by the scope of designation;

(ab) to review and approve the criteria of the competent authorities of Member States in respect of point (aa);

(ac) to oversee the coordination group of notified bodies as specified in Article 37;

(ad) to support the Commission in providing an overview of vigilance data and market surveillance activities, including any preventive health protection measures taken, on a six-monthly basis. This information shall be accessible through the European databank in Article 25; **[Am. 261]**

~~(b) to contribute to the scrutiny of certain conformity assessments pursuant to Article 42;~~ **[Am. 190]**

(c) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of the clinical evaluation by manufacturers and the assessment by notified bodies;

(d) to assist the competent authorities of the Member States in their coordination activities in the fields of clinical performance studies, vigilance and market surveillance;

(e) to provide advice and assist the Commission, at its request, in its assessment of any issue related to the implementation of this Regulation;

(f) to contribute to harmonised administrative practice with regard to *in vitro* diagnostic medical devices in the Member States.

Article 78

European Union reference laboratories

1. For specific devices, or a category or group of devices, or for specific hazards related to a category or group of devices, the Commission may designate, by means of implementing acts, one or more European Union reference laboratories, hereinafter referred to as 'EU reference laboratories', that satisfy the criteria set out in paragraph 3. The Commission shall only designate laboratories for which a Member State or the Commission's Joint Research Centre have submitted an application for designation.

2. Within the scope of their designation, the EU reference laboratories shall, where appropriate, have the following tasks:

   (a) to verify compliance of class D devices with the applicable CTS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as provided for in the second subparagraph of Article 40(2);

(b) to carry out appropriate ***laboratory*** tests on samples of manufactured class D devices ~~or batches of class D devices, as provided for in the Section 5.7 of Annex VIII and in Section 5.1 of~~ ***on request of competent authorities on samples collected during market surveillance activities under Article 65 and of notified bodies on samples collected during unannounced inspections under*** Annex ~~X~~***VIII section 4.4***; **[Am. 191]**

(c) to provide scientific and technical assistance to the Commission, the Member States and notified bodies in relation to the implementation of this Regulation;

(d) to provide scientific advice ***and technical assistance*** regarding ***the definition of*** the state of the art in relation to specific devices, or a category or group of devices; **[Am. 192]**

(e) to set up and manage a network of national reference laboratories and publish a list of the participating national reference laboratories and their respective tasks;

(f) to contribute to the development of appropriate testing and analysis methods to be applied for conformity assessment procedures ~~and~~***, in particular for batch verification of class D devices and for*** market surveillance; **[Am. 193]**

(g) to collaborate with notified bodies in the development of best practices for the performance of conformity assessment procedures;

(h) to provide recommendations on suitable reference materials and reference measurement procedures of higher metrological order;

(i) to contribute to the development of ~~standards at~~ ***CTS and of*** international ~~level~~ ***standards***; **[Am. 194]**

(j) to provide scientific opinions in response to consultations by notified bodies in accordance with this Regulation.

3. EU reference laboratories shall satisfy the following criteria:

(a) to have appropriately qualified staff with adequate knowledge and experience in the field of the *in vitro* diagnostic medical devices for which they are designated; ***appropriate knowledge and experience shall be based on:***

(i) experience of assessing high-risk IVDs and of carrying out the relevant laboratory tests;

(ii) in-depth knowledge of high-risk in-vitro diagnostic medical devices and relevant technologies;

(iii) proven laboratory experience in one of the following areas: testing or calibration laboratory, supervisory authority or institution, national reference laboratory for class D devices, quality control of in-vitro diagnostic medical devices, development of reference materials for IVDs, calibration of diagnostic medical devices; laboratories or blood banks which experimentally assess and use high-risk IVDs or, where applicable, manufacture them in-house;

(iv) knowledge and experience of product or batch testing, quality checks, design, manufacture and use of IVDs;

(v) knowledge of the health risks faced by patients, their partners and recipients of blood/organ/tissue donations/preparations associated with the use and, in particular, malfunctioning of high-risk IVDs;

(vi) knowledge of this Regulation and of applicable laws, rules and guidelines, knowledge of the CTS, applicable harmonized standards, product-specific requirements and relevant guidance documents;

(vii) participation in relevant external and internal quality assessment schemes organised by international or national organisations. **[Am. 195]**

(b) to possess the necessary equipment and reference material to carry out the tasks assigned to them;

(c) to have the necessary knowledge of international standards and best practices;

(d) to have an appropriate administrative organisation and structure;

(e) to ensure that their staff observe the confidentiality of the information and data obtained in carrying out their tasks;

(f) to act in the public interest and in an independent manner;

(g) to ensure that their staff do not have financial or other interests in the *in vitro* diagnostic medical device industry which could affect their impartiality, declare any other direct and indirect interests they may have in the *in vitro* diagnostic medical device industry and update this declaration whenever a relevant change occurs.

4. EU reference laboratories may be granted a Union financial contribution.

The Commission may adopt, by means of implementing acts, the modalities and the amount of the grant of a Union financial contribution to EU reference laboratories, taking into account the objectives of protection of health and safety, support of innovation and cost-effectiveness. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

5. Where notified bodies or Member States request scientific or technical assistance or a scientific opinion from an EU reference laboratory, they ~~may~~ ***shall*** be required to pay fees to wholly ~~or partially~~ cover the costs incurred by that laboratory in carrying out the requested task according to a set of predetermined and transparent terms and conditions. **[Am. 196]**

6. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 for the following purposes:

(a) amending or supplementing the tasks of EU reference laboratories referred to in paragraph 2 and the criteria to be satisfied by EU reference laboratories referred to in paragraph 3.

(b) setting out the structure and the level of the fees referred to in paragraph 5 which may be levied by an EU reference laboratory for providing scientific opinions in response to consultations by notified bodies in accordance with this Regulation, taking into account the objectives of protection of human health and safety, support of innovation and cost-effectiveness.

7. EU reference laboratories shall be subject to controls, including on-site visits and audits, by the Commission to verify compliance with the requirements of this Regulation. If these controls find that a laboratory is not complying with those requirements for which they have been designated, the Commission, by means of implementing acts, shall take appropriate measures, including the withdrawal of the designation.

Article 79

Device registers

The Commission and the Member States shall take all appropriate measures to ~~encourage~~ ***ensure*** the establishment of registers for ~~specific types of~~ ***in vitro diagnostic*** devices to gather post-market experience related to the use of such devices***. Registers for class C and D devices shall be systematically established***. Such registers shall contribute to the independent evaluation of the long-term safety and performance of devices. **[Am. 197]**

Chapter ~~IX~~*X*

Confidentiality, data protection, funding, penalties [Am. 200]

Article 80

Confidentiality

1. Unless otherwise provided in this Regulation and without prejudice to existing national provisions and practices in the Member States on medical confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:

(a) personal data in compliance with Directive 95/46/EC and Regulation (EC) No 45/2001;

(b) commercial interests of a natural or legal person, including intellectual property rights;

(c) the effective implementation of this Regulation, in particular for the purpose of inspections, investigations or audits.

2. Without prejudice to paragraph 1, information exchanged between competent authorities and between competent authorities and the Commission on condition of confidentiality shall remain confidential unless the originating authority has agreed to its disclosure.

3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

4. The Commission and Member States may exchange confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

Article 81

Data protection

1. Member States shall apply Directive 95/46/EC to the processing of personal data carried out in the Member States pursuant to this Regulation.

2. Regulation (EC) No 45/2001 shall apply to the processing of personal data carried out by the Commission pursuant to this Regulation.

Article 82

Levy of fees

This Regulation shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this Regulation, provided that the level of the fees is ***comparable and*** set in a transparent manner and on the basis of cost recovery principles. They shall inform the Commission and the other Member States at least three months before the structure and level of fees is to be adopted. **[Am. 198]**

Article 83

Penalties

The Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. ***The dissuasive nature of the penalty shall be determined in relation to the financial benefit obtained as a result of the infringement.*** The Member States shall notify those provisions to the Commission by …* and shall notify it without delay of any subsequent amendment affecting them. **[Am. 199]**

Chapter ~~X~~*XI*

Final provisions [Am. 201]

Article 84

Committee procedure

1. The Commission shall be assisted by the Committee on Medical Devices set up by Article 88 of Regulation (EU) [Ref. of future Regulation on medical devices].

* 3 months prior to the date of application of this Regulation.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 or Article 5, as appropriate, shall apply.

Article 85

Exercise of the delegation

1. The power to adopt the delegated acts referred to in Articles 4(6), 8(2), 15(4), 22(7), 23(7), 27(2), 38(2), 39(4), 40(10), 43(5), 49(7), 51(3), 72(4) and 78(6) is conferred on the Commission subject to the conditions laid down in this Article.

2. The delegation of power referred to in Articles 4(6), 8(2), 15(4), 22(7), 23(7), 27(2), 38(2), 39(4), 40(10), 43(5), 49(7), 51(3), 72(4) and 78(6) shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.

3. The delegation of power referred to in Articles 4(6), 8(2), 15(4), 22(7), 23(7), 27(2), 38(2), 39(4), 40(10), 43(5), 49(7), 51(3), 72(4) and 78(6) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following its publication in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to any of the Articles listed in paragraph 1 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period may be extended by two months at the initiative of the European Parliament or the Council.

Article 86

Urgency procedure for delegated acts

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 85. In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or the Council.

Article 87

Transitional provisions

1. From …* any publication of a notification in respect of a notified body in accordance with Directive 98/79/EC shall become void.

* The date of application of this Regulation.

2. Certificates issued by notified bodies in accordance with Directive 98/79/EC prior to the entry into force of this Regulation shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex VI of Directive 98/79/EC which shall become void at the latest two years after the date of application of this Regulation.

   Certificates issued by notified bodies in accordance with Directive 98/79/EC after the entry into force of this Regulation shall become void at the latest two years after the date of application of this Regulation.

3. By way of derogation from Directive 98/79/EC, devices which comply with this Regulation may be placed on the market before its date of application.

4. By way of derogation from Directive 98/79/EC, conformity assessment bodies which comply with this Regulation may be designated and notified before its date of application. Notified bodies which are designated and notified in accordance with this Regulation may apply the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation before its date of application.

5. By way of derogation from Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC, manufacturers, authorised representatives, importers and notified bodies who, during the period from [date of application] until [18 months after date of application], comply with Article 23(2) and (3) and Article 43(4) of this Regulation shall be considered to comply with the laws and regulations adopted by Member States in accordance with Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC as specified in Decision 2010/227/EU.

6. Authorisations granted by competent authorities of the Member States in accordance with Article 9(12) of Directive 98/79/EC shall keep the validity indicated in the authorisation.

Article 88

Evaluation

No later than …[*], the Commission shall assess the application of this Regulation and establish an evaluation report on the progress towards achievement of the objectives of this Regulation including an assessment of resources required to implement this Regulation.

[*] Five years after the date of application of this Regulation.

Article 89

Repeal

Directive 98/79/EC is repealed with effect from ...* with the exception of Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC which are repealed with effect from ...**.

References to the repealed Directive shall be understood as reference to this Regulation and shall be read in accordance with the correlation table laid down in Annex XIV.

Article 90

Entry into force and date of application

1. This Regulation shall enter into force on the twentieth day after its publication in the *Official Journal of the European Union.*

2. It shall apply from …***.

3. By way of derogation from paragraph 2, the following shall apply:

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* The date of application of this Regulation.

** 18 months after the date of application of this Regulation.

*** ~~five~~ ***three*** years after entry into force of this Regulation.

(a) Article 23~~(2) and (3) and Article 43(4)~~ ***(1)*** shall apply from …[*]

(b) Articles 26 to 38 shall apply from …[**] . However, prior to …[***] , the obligations on notified bodies emanating from the provisions in Articles 26 to 38 shall apply only to those bodies which submit an application for notification in accordance with Article 29 of this Regulation.

(ba) Article 74 shall apply from [****];

(bb) Articles 75 to 77 shall apply from...[*****];

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[*] ~~18 months~~ ***30 months*** after ~~date of application referred to in paragraph 2~~ ***entry into force*** of this Regulation.

[**] Six months after the entry into force of this Regulation.

[***] The date of application of this Regulation.

[****] ***Six months after the entry into force of this Regulation.***

[*****] ***12 months after the entry into force of this Regulation.***

(bc) Article 59 to 64 shall apply from...* ;

(bd) Article 78 shall apply from ...*.

3a. The implementing acts referred to in Articles 31(4), 40(9), 42(8), 46(2) and Articles 58 and 64 shall be adopted within ...** **[Am. 202]**

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at ...

For the European Parliament	*For the Council*
The President	*The President*

* ***24 months after the entry into force of this Regulation.***

** ***12 months after the entry into force of this Regulation.***

ANNEXES

ANNEX I

GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

I. GENERAL REQUIREMENTS

1. The devices shall achieve the performance intended by the manufacturer and be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose, taking into account the generally acknowledged state of the art. They shall not compromise, directly or indirectly, the clinical condition or the safety of the patients, or the safety or health of users or, where applicable, other persons, provided that any risks or limits to performance which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

   This shall include:

   – reducing as far as possible the risk of error due to ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and

   – consideration of the technical knowledge, experience, education or training, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

2. The solutions adopted by the manufacturer for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, the manufacturer shall manage the risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. The manufacturer shall apply the following principles in the priority order listed:

   (a) identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse;

   (b) eliminate risks as far as possible through inherently safe design and manufacture;

   (c) reduce as far as possible the remaining risks by taking adequate protection measures, including alarms; and

   (d) provide training to users and/or inform users of any residual risks.

3. The characteristics and performances of the device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions. When no lifetime is stated, the same applies for the lifetime reasonably to be expected of a device of that kind, having regard to the intended purpose and the anticipated use of the device.

4. The devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use will not be adversely affected by transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.

5. All known and foreseeable risks, and any undesirable effects, shall be minimised and be acceptable when weighed against the benefits to the patients of the intended performance of the device during normal conditions of use.

II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION

6. Performance characteristics

6.1. The devices shall be designed and manufactured in such a way that the performance characteristics support the intended purpose, based on appropriate scientific and technical methods. They shall achieve the performances, as stated by the manufacturer and in particular, where appropriate:

(a) the analytical performance, such as accuracy (trueness and precision), bias, analytical sensitivity, analytical specificity, limits of detection and quantitation, measuring range, linearity, cut-off, repeatability, reproducibility, including determination of appropriate criteria for specimen collection and handling and control of known relevant endogenous and exogenous interference, cross-reactions; and

(b) the clinical performance, ***including measures of clinical validity*** such as diagnostic sensitivity, diagnostic specificity, positive and negative predictive value, likelihood ratio, expected values in normal or affected populations***; and, where appropriate, measures of clinical utility. In the case of companion diagnostics, evidence of the clinical utility of the device for the intended purpose (selection of patients with a previously diagnosed condition or predisposition eligible for a targeted therapy) is required. For a companion diagnostic, the manufacturer should supply clinical evidence relating to the impact of a positive or negative test on (1) patient care; and (2) health outcomes, when used as directed with the stated therapeutic intervention***. **[Am. 203]**

6.2. The performance characteristics of the device need to be maintained during the lifetime of the device as indicated by the manufacturer.

6.3. Where the performance of devices depends on the use of calibrators and/or control materials, the metrological traceability of values assigned for a given analyte to such calibrators and/or control materials shall be assured through available and suitable reference measurement procedures and/or available and suitable reference materials of a higher metrological order. The device shall be designed and manufactured to enable the user to provide measurement results in patient specimens metrologically traceable to available and suitable higher order reference materials and/or reference measurement procedures following the instructions and information provided by the manufacturer.

7. Chemical, physical and biological properties

7.1. The devices shall be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Chapter I 'General Requirements'.

Particular attention shall be paid to the possibility of impairment of analytical performance due to incompatibility between the materials used and the specimens and/or analyte to be detected (such as biological tissues, cells, body fluids and micro-organisms), taking account of the intended purpose of the device.

7.2. The devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed and to the duration and frequency of exposure.

7.3. The devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances that may leach or leak from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[1], and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council[2] .

7.4. The devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional ingress or egress of substances into or from the device, taking into account the device and the nature of the environment in which it is intended to be used.

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1 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

2 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

8. Infection and microbial contamination

8.1. The devices and their manufacturing processes shall be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user, professional or lay, or, where applicable, other persons.

The design shall:

(a) allow easy and safe handling;

and, where necessary

(b) reduce as far as possible and appropriate any microbial leakage from the device and/or microbial exposure during use;

(c) prevent microbial contamination of the device or specimen.

8.2. The devices labelled either as sterile or as having a special microbiological state shall be designed, manufactured and packaged to ensure that they remain so when placed on the market, and remain so under the transport and storage conditions specified by the manufacturer, until the protective packaging is damaged or opened.

8.3. The devices labelled either as sterile or as having a special microbiological state shall have been processed, manufactured and, if applicable, sterilised by appropriate validated methods.

8.4. The devices intended to be sterilised shall be manufactured in appropriately controlled (e.g. environmental) conditions.

8.5. Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the device indicated by the manufacturer and, if the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.

8.6. The labelling of the devices shall distinguish between identical or similar products placed on the market in both sterile and non-sterile condition.

9. Devices incorporating materials of biological origin

9.1. Where the devices include tissues, cells and substances originating from animals, the processing, preservation, testing and handling of tissues, cells and substances of such origin shall be carried out so as to provide optimal safety for user, professional or lay, or other person.

In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain devices if the activity of the virus and other transmissible agent are integral to the intended purpose of the device or when such elimination or inactivation process would compromise the performance of the device.

9.2. Where the devices include human tissues, cells or substances, the selection of sources, donors and/or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin shall be carried out so as to provide optimal safety for user, professional or lay, or other person.

In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain devices if the activity of the virus and other transmissible agent are integral to the intended purpose of the device or when such elimination or inactivation process would compromise the performance of the device.

9.3. Where the devices include cells or substances of microbial origin, the processing, preservation, testing and handling of cells and substances shall be carried out so as to provide optimal safety for user, professional or lay, or other person.

In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain devices if the activity of the virus and other transmissible agent are integral to the intended purpose of the device or when such elimination or inactivation process would compromise the performance of the device.

10. Interaction of devices with their environment

10.1. If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system, shall be safe and shall not impair the specified performances of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle shall be designed and constructed in such a way as to minimise all possible risks from incorrect connection.

10.2. The devices shall be designed and manufactured in such a way as to remove or reduce as far as possible and appropriate:

(a) the risks of injury to user, professional or lay, or other person in connection with their physical and ergonomic features;

(b) the risks of use error due to the ergonomic features, human factors and the environment in which the device is intended to be used;

(c) the risks connected with any foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature variations or radio signal interferences;

(d) the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use;

(e) the risks associated with the possible negative interaction between software and the environment within which it operates and interacts;

(f) the risks of accidental ingress of substances into the device;

(g) the risk of incorrect identification of specimens;

(h) the risks of any foreseeable interference with other devices.

10.3. The devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices whose intended purpose includes exposure to or use in association with flammable substances or substances which could cause combustion.

10.4. The devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance, where such is necessary to achieve the performances intended, can be done safely.

10.5. The devices that are intended to be operated together with other devices or products shall be designed and manufactured in such as way that the interoperability is reliable and safe.

10.6. The devices shall be designed and manufactured in such a way as to facilitate the safe disposal of the device and/or of any waste substances by the user, professional or lay, or other person.

10.7. The measuring, monitoring or display scale (including colour change and other visual indicators) shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose of the device.

11. Devices with a measuring function

11.1. The devices having a primary analytical measuring function shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability of measurement within appropriate accuracy limits, taking into account the intended purpose of the device and of available and appropriate reference measurement procedures and materials. The accuracy limits shall be specified by the manufacturer.

11.2. The measurements made by devices with a measuring function and expressed in legal units shall conform to the provisions of Council Directive 80/181/EEC[1].

12. Protection against radiation

12.1. The devices shall be designed, manufactured and packaged in such a way that exposure of user, professional or lay, or other persons to the emitted radiation (intended, unintended, stray or scattered) is reduced as far as possible.

12.2. When the devices are intended to emit potentially hazardous, visible and/or invisible radiation, they shall as far as possible be:

1 OJ L 39, 15.2.1980.

(a) designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted; and

(b) fitted with visual displays and/or audible warnings of such emissions.

12.3. The operating instructions for devices emitting radiation shall give detailed information as to the nature of the emitted radiation, means of protecting the user, and on ways of avoiding misuse and of eliminating the risks inherent in installation.

13. Software incorporated in devices and standalone software

13.1. The devices that incorporate electronic programmable systems, including software, or standalone software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance according to the intended purpose. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible and appropriate consequent risks.

13.2. For the devices that incorporate software or for standalone software that are devices in themselves, the software shall be developed and manufactured according to the state of the art taking into account the principles of development life cycle, risk management, verification and validation.

13.3. Software referred to in this Section that are intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards to level of light or noise).

14. Devices connected to or equipped with an energy source

14.1. For the devices connected to or equipped with an energy source, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible and appropriate consequent risks.

14.2. The devices where the safety of the patient depends on an internal power supply in the device shall be equipped with a means of determining the state of the power supply.

14.3. The devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the intended environment.

14.4. The devices shall be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.

14.5. The devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the user, professional or lay, or other person both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.

15. Protection against mechanical and thermal risks

15.1. The devices shall be designed and manufactured in such a way as to protect the user, professional or lay, or other person against mechanical risks.

15.2. The devices shall be sufficiently stable under the foreseen operating conditions. They shall be suitable to withstand stresses inherent in the foreseen working environment, and to retain this resistance during the expected lifetime of the devices, subject to any inspection and maintenance requirements as indicated by the manufacturer.

15.3. Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means shall be incorporated.

Any guards or other means included with the device to provide protection, in particular against moving parts, shall be secure and shall not interfere with access for the normal operation of the device, or restrict routine maintenance of the device as intended by the manufacturer.

15.4. The devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.

15.5. The devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.

15.6. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user, professional or lay, or other person has to handle shall be designed and constructed in such a way as to minimise all possible risks.

15.7. Errors likely to be made when fitting or refitting, or connecting or reconnecting, certain parts before or during use which could be a source of risk must be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings.

The same information must be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.

15.8. Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.

16. Protection against the risks posed by devices intended by the manufacturer for self-testing ~~or near-patient testing~~

16.1. The devices intended for self-testing ~~or near-patient testing~~ shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to the intended user and the influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment. The information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply.

16.2. The devices intended for self-testing ~~or near-patient testing~~ shall be designed and manufactured in such a way as to

– ensure that the device is easy to use by the intended user at all stages of the procedure; and

– reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, the specimen, and also in the interpretation of the results.

16.3. The devices intended for self-testing ~~and near-patient testing~~ shall, where reasonably possible, include a procedure by which the intended user can: **[Am. 204]**

– verify that, at the time of use, the device will perform as intended by the manufacturer; and

– be warned if the device has failed to provide a valid result.

III. REQUIREMENTS REGARDING INFORMATION SUPPLIED WITH THE DEVICE

17. Label and instructions for use

17.1. General requirements regarding the information supplied by the manufacturer

Each device shall be accompanied by the information needed to identify the device and its manufacturer, and communicate safety and performance related information to the user, professional or lay, or other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, ***and must be made available on the manufacturer's website*** taking into account the following: **[Am. 206]**

(i) The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams. Some devices may include separate information for the professional user and the lay person.

(ii) The information required on the label, shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit, and/or on the packaging of multiple devices.

Where multiple devices are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided.

(iii) In duly justified and exceptional cases instructions for use may not be needed or may be abbreviated if the device can be used safely and as intended by the manufacturer without any such instructions for use.

(iv) Labels shall be provided in a human-readable format but may be supplemented by machine-readable forms, such as radio-frequency identification (RFID) or bar codes.

(v) When the device is intended for professional use only , instructions for use may be provided to the user in non-paper format (e.g. electronic), except when the device is intended for near-patient testing.

(vi) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, ~~contraindications,~~ precautions or warnings in the information supplied by the manufacturer. **[Am. 207]**

(vii) Where appropriate, this information should take the form of internationally recognised symbols. Any symbol or identification colour used shall conform to the harmonised standards or CTS. In areas for which no standards or CTS exist, the symbols and colours shall be described in the documentation supplied with the device.

(viii) In the case of devices containing a substance or a mixture which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, relevant hazard pictograms and labelling requirements of Regulation (EC) No 1272/2008 shall apply. Where there is insufficient space to put all the information on the device itself or on its label, the relevant hazard pictograms shall be put on the label and the other information required by that Regulation shall be given in the instructions for use.

(ix) The provisions of Regulation (EC) No 1907/2006 on the safety data sheet shall apply, unless all relevant information as appropriate is already made available by the instructions for use.

17.2. Information on the label

The label shall bear the following particulars:

(i) The name or trade name of the device;

(ii) The details strictly necessary for the user to identify the device and, where it is not obvious for the user, the intended purpose of the device;

(iii) The name, registered trade name or registered trade mark of the manufacturer and the address of his registered place of business at which he can be contacted and his location be established;

(iv) For imported devices, the name, registered trade name or registered trade mark of the authorised representative established within the Union and the address of his registered place of business at which he can be contacted and his location be established;

(v) An indication that the device is for *in vitro* diagnostic use;

(vi) The batch code/lot number or the serial number of the device preceded by the word LOT or SERIAL NUMBER or an equivalent symbol, as appropriate;

(vii) Where applicable, the unique device identification (UDI);

(viii) An unambiguous indication of the date until when the device may be used safely, without degradation of performance, expressed at least as the year, the month and, where relevant, the day, in that order;

(ix) Where there is no indication of the date until when it may be used safely, the year of manufacture. This year of manufacture may be included as part of the batch or serial number, provided the date is clearly identifiable;

(x) Where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of these, or other terms which accurately reflect the contents of the package;

(xi) An indication of any special storage and/or handling condition that applies;

(xii) Where appropriate, an indication of the sterile state of the device and the sterilisation method, or a statement indicating any special microbiological state or state of cleanliness;

(xiii) Warnings or precautions to be taken that need to be brought to the immediate attention of the user, professional or lay, or other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use;

(xiv) Where applicable, any particular operating instructions;

~~(xv) If the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;~~ **[Am. 208]**

(xvi) If the device is intended for self-testing or near-patient testing, an indication of that fact;

(xvii) If the device is for performance evaluation only, an indication of that fact;

(xviii) Where device kits include individual reagents and articles that may be made available as separate devices, each of these devices shall comply with the labelling requirements contained in this Section;

(xix) Wherever reasonable and practicable, the devices and separate components shall be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.

17.3. Information in the instructions for use

17.3.1. The instructions for use shall contain the following particulars:

(i) The name or trade name of the device;

(ii) The device's intended purpose ***which may include***: **[Am. 209]**

– what is detected and/or measured;

– its function (e.g. screening, monitoring, diagnosis or aid to diagnosis***, prognosis, companion diagnostic***); **[Am. 210]**

– the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;

– whether it is automated or not;

– whether it is qualitative, semi-quantitative or quantitative;

– the type of specimen(s) required;

– where applicable, the testing population; and

– ***for companion diagnostics, the relevant target population and directions for use with associated therapeutic(s).*** **[Am. 211]**

(iii) An indication that the device is for *in vitro* diagnostic use;

(iv) The intended user, as appropriate (e.g. healthcare professionals, lay person);

(v) The test principle;

(vi) A description of the reagents, calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only);

(vii) A list of materials provided and a list of special materials required but not provided;

(viii) For devices intended for use together with other devices and/or general purpose equipment:

- information to identify such devices or equipment, in order to obtain a safe combination, and/or
- information on any known restrictions to combinations of devices and equipment.

(ix) An indication of any special storage (e.g. temperature, light, humidity, etc.) and/or handling conditions which apply;

(x) In-use stability which may include the storage conditions, and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions, where this is relevant;

(xi) If the device is supplied as sterile, an indication of its sterile state, the sterilisation method and instructions in the event of the sterile packaging being damaged before use;

(xii) Information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device. This information shall cover, where appropriate:

- warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance;
- warnings, precautions and/or measures to be taken in regards to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;
- warnings, precautions and/or measures to be taken in regards to the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or other procedures (e.g. electromagnetic interference emitted by the device affecting other equipment);
- precautions related to materials incorporated into the device that are carcinogenic, mutagenic or toxic, or that have endocrine disrupting properties or that could result in sensitisation or allergic reaction of the patient or user;

– if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;

– if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, decontamination, packaging and, where appropriate, the validated method of re-sterilization. Information shall be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses.

(xiii) Any warnings and/or precautions related to potentially infectious material that is included in the device;

(xiv) Where relevant, requirements for special facilities (e.g. clean room environment) or special training (e.g. radiation safety), or particular qualifications of the device intended user;

(xv) Conditions for collection, handling, and preparation of the specimen;

(xvi) Details of any preparatory treatment or handling of the device before it is ready for use (e.g. sterilisation, final assembly, calibration, etc.);

(xvii) The information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:

- details of the nature, and frequency, of preventative and regular maintenance, including cleaning and disinfection;
- identification of any consumable components and how to replace them;
- information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime;
- methods of mitigating the risks encountered by persons involved in installing, calibrating or servicing devices.

(xviii) Where relevant, recommendations for quality control procedures;

(xix) The metrological traceability of values assigned to calibrators and trueness-control materials, including identification of applicable reference materials and/or reference measurement procedures of higher order;

(xx) Assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing shall be considered;

(xxi) Analytical performance characteristics, such as sensitivity, specificity, and accuracy, repeatability, reproducibility, limits of detection and measurement range, including information needed for the control of known relevant interferences, limitations of the method and information about the use of available reference measurement procedures and materials by the user;

(xxii) Where relevant, clinical performance characteristics, such as diagnostic sensitivity and diagnostic specificity;

(xxiii) Where relevant, reference intervals;

(xxiv) Information on interfering substances or limitations (e.g. visual evidence of hyperlipidaemia or haemolysis, age of specimen) that may affect the performance of the device;

(xxv) Warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories, and the consumables used with it, if any. This information shall cover, where appropriate:

– infection or microbial hazards (e.g. consumables contaminated with potentially infectious substances of human origin);

– environmental hazards (e.g. batteries or materials that emit potentially hazardous levels of radiation);

– physical hazards (e.g. explosion).

(xxvi) The name, registered trade name or registered trade mark of the manufacturer and the address of his registered place of business at which he can be contacted and his location be established, together with a telephone number and/or fax number and/or website address to obtain technical assistance;

(xxvii) Date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use;

(xxviii) A notice to the user, professional or lay, that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is established;

(xxix) Where device kits include individual reagents and articles that may be made available as separate devices, each of these devices shall comply with the instructions for use requirements contained in this Section.

17.3.2. In addition, the instructions for use for devices intended for self-testing or near-patient testing shall comply with the following principles:

(i) Details of the test procedure shall be given, including any reagent preparation, specimen collection and/or preparation and information on how to run the test and read the results;

(ia) The instruction for use shall be understandable to a layperson and reviewed by the representatives of relevant stakeholders, including patient and healthcare professionals' organisations and manufacturers' associations; **[Am. 212]**

(ii) The results need to be expressed and presented in a way that is readily understood by the intended user;

(iii) Information needs to be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result), on the test limitations and on the possibility of false positive or false negative result. Information shall also be provided as to any factors that can affect the test result (e.g. age, gender, menstruation, infection, exercise, fasting, diet or medication);

(iv) for devices intended for self-testing, the information provided shall include a statement clearly directing that the user should not take any decision of medical relevance without first consulting the appropriate healthcare professional;

(v) for devices intended for self-testing used for the monitoring of an existing disease, the information shall specify that the patient should only adapt the treatment if he has received the appropriate training to do so.

ANNEX II

TECHNICAL DOCUMENTATION

The technical documentation and, if applicable, the summary technical documentation (STED) to be drawn up by the manufacturer shall include in particular the following elements:

1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES

1.1. Device description and specification

(a) product or trade name and a general description of the device, including its intended purpose;

(b) the UDI device identifier as referred to in item (i) of point (a) of Article 22(1) attributed by the manufacturer to the device in question, as soon as identification of this device shall be based on a UDI system, or otherwise clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability;

(c) the intended purpose of the device which may include:

(i) what is detected and/or measured;

(ii) its function (e.g. screening, monitoring, diagnosis or aid to diagnosis***, prognosis, companion diagnosis***); **[Am. 213]**

(iii) the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;

(iv) whether it is automated or not;

(v) whether it is qualitative, semi-quantitative or quantitative;

(vi) the type of specimen(s) required;

(vii) where applicable, the testing population;

(viii) the intended user;

(viiia) for companion diagnostics, the relevant target population and directions for use with the associated therapeutic(s). **[Am. 214]**

(d) the description of the principle of the assay method or instrument principles of operation;

(e) the risk class of the device and the applicable classification rule according to Annex VII;

(f) the description of the components and where appropriate, the description of the reactive ingredients of relevant components (such as antibodies, antigens, nucleic acid primers);

and where applicable:

(g) the description of the specimen collection and transport materials provided with the device or descriptions of specifications recommended for use;

(h) for instruments of automated assays: the description of the appropriate assay characteristics or dedicated assays;

(i) for automated assays: a description of the appropriate instrumentation characteristics or dedicated instrumentation;

(j) a description of any software to be used with the device;

(k) a description or complete list of the various configurations/variants of the device that will be made available;

(l) a description of the accessories, other *in vitro* diagnostic medical devices and other products, which are intended to be used in combination with the device.

1.2. Reference to previous and similar generations of the device

(a) an overview of the manufacturer's previous generation(s) of the device, if such exist;

(b) an overview of the manufacturer's similar devices available on the EU or international markets, if such exist.

2. INFORMATION SUPPLIED BY THE MANUFACTURER

(a) a complete set of

– the label(s) on the device and on its packaging;

– the instructions for use;

(b) a list of the language variants for the Member States where the device is envisaged to be marketed.

3. DESIGN AND MANUFACTURING INFORMATION

3.1. Design information

Information to allow a general understanding of the design stages applied to the device.

This shall include:

(a) the description of the critical ingredients of the device such as antibodies, antigens, enzymes and nucleic acid primers provided or recommended for use with the device;

(b) for instruments, the description of major subsystems, analytical technology (e.g. operating principles, control mechanisms), dedicated computer hardware and software;

(c) for instruments and software, the overview of the entire system;

(d) for standalone software, the description of the data interpretation methodology (i.e. algorithm);

(e) for devices intended for self-testing or near-patient testing devices the description of the design aspects that make them suitable for self-testing or near-patient testing.

3.2. Manufacturing information

(a) Information to allow a general understanding of the manufacturing processes such as production, assembly, final product testing, and packaging of the finished device. More detailed information needs to be provided for the audit of the quality management system or other applicable conformity assessment procedures;

(b) identification of all sites, including suppliers and sub-contractors, where ***critical*** manufacturing activities are performed. **[Am. 265]**

4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

The documentation shall contain information regarding the solutions adopted to meet the general safety and performance requirements laid down in Annex I. This information may take the form of a checklist identifying:

(a) the general safety and performance requirements that apply to the device and why others do not apply;

(b) the method(s) used to demonstrate conformity with each applicable general safety and performance requirement;

(c) the harmonised standards or CTS applied or other method(s) employed;

(d) the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CTS or other method employed to demonstrate conformity with the general safety and performance requirements. This information shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.

5. RISK/BENEFIT ANALYSIS AND RISK MANAGEMENT

The documentation shall contain a summary of

(a) the risk/benefit analysis referred to in Section 1 and 5 of Annex I; and

(b) the solutions adopted and the results of the risk management referred to in Section 2 of Annex I.

6. PRODUCT VERIFICATION AND VALIDATION

The documentation shall contain the results of verification and validation testing and/or studies undertaken to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements.

This includes:

6.1 Information on analytical performance

6.1.1 Specimen type

This section shall describe the different specimen types that can be used, including their stability (e.g. storage and where applicable transport conditions) and storage conditions (e.g. duration, temperature limits and freeze/thaw cycles).

6.1.2 Analytical performance characteristics

6.1.2.1 Accuracy of measurement

(a) Trueness of measurement

This section shall provide information on the trueness of the measurement procedure and summarise the data in sufficient detail to allow assessment of the adequacy of the means selected to establish the trueness. Trueness measures apply to both quantitative and qualitative assays only when a reference standard or method is available.

(b) Precision of measurement

This section shall describe repeatability and reproducibility studies.

6.1.2.2 Analytical sensitivity

This section shall include information about the study design and results. It shall provide a description of specimen type and preparation including matrix, analyte levels, and how levels were established. The number of replicates tested at each concentration shall also be provided as well as a description of the calculation used to determine assay sensitivity.

6.1.2.3 Analytical specificity

This section shall describe interference and cross reactivity studies to determine the analytical specificity in the presence of other substances/agents in the specimen.

Information shall be provided on the evaluation of potentially interfering and cross reacting substances/agents on the assay, on the substance/agent type and concentration tested, specimen type, analyte test concentration, and results.

Interferents and cross reacting substances/agents, which vary greatly depending on the assay type and design, could derive from exogenous or endogenous sources such as:

(a) substances used for patient treatment (e.g. medicinal products);

(b) substances ingested by the patient (e.g. alcohol, foods);

(c) substances added during specimen preparation (e.g. preservatives, stabilisers);

(d) substances encountered in specific specimens types (e.g. haemoglobin, lipids, bilirubin, proteins);

(e) analytes of similar structure (e.g. precursors, metabolites) or medical conditions unrelated to the test condition including specimens negative for the assay but positive for a condition that may mimic the test condition.

6.1.2.4 Metrological traceability of calibrator and control material values

6.1.2.5 Measuring range of the assay

This section shall include information on the measuring range (linear and non-linear measuring systems) including the limit of detection and describe information on how these were established.

This information shall include a description of specimen type, number of specimen, number of replicates, and preparation including information on matrix, analyte levels and how levels were established. If applicable, a description of high dose hook effect and the data supporting the mitigation (e.g. dilution) steps shall be added.

6.1.2.6 Definition of assay cut-off

This section shall provide a summary of analytical data with a description of the study design including methods for determining the assay cut-off, including:

(a) the population(s) studied (demographics / selection / inclusion and exclusion criteria / number of individuals included);

(b) method or mode of characterisation of specimens; and

(c) statistical methods e.g. Receiver Operator Characteristic (ROC) to generate results and if applicable, define grey-zone/equivocal zone.

6.2 Information on clinical performance

Where applicable, the documentation shall contain data on the clinical performance of the device.

The clinical evidence report referred to in Section 3 of Annex XII shall be included and~~/or~~ fully referenced in the technical documentation. **[Am. 215]**

6.3 Stability (excluding specimen stability)

This section shall describe claimed shelf life, in use stability and shipping stability studies.

6.3.1 Claimed shelf life

This section shall provide information on stability testing studies to support the claimed shelf life. Testing shall be performed on at least three different lots manufactured under conditions that are essentially equivalent to routine production conditions (these lots do not need to be consecutive lots). Accelerated studies or extrapolated data from real time data are acceptable for initial shelf life claim but need to be followed up with real time stability studies.

Such detailed information shall describe:

(a) the study report (including the protocol, number of lots, acceptance criteria and testing intervals);

(b) when accelerated studies have been performed in anticipation of the real time studies, the method used for accelerated studies;

(c) the conclusions and claimed shelf life.

6.3.2 In-use stability

This section shall provide information on in-use stability studies for one lot reflecting actual routine use of the device (real or simulated). This may include open vial stability and/or, for automated instruments, on board stability.

In the case of automated instrumentation if calibration stability is claimed, supporting data shall be included.

Such detailed information shall describe:

(a) the study report (including the protocol, acceptance criteria and testing intervals);

(b) the conclusions and claimed in-use stability.

6.3.3 Shipping stability

This section shall provide information on shipping stability studies for one lot to evaluate the tolerance of products to the anticipated shipping conditions.

Shipping studies can be done under real and/or simulated conditions and shall include variable shipping conditions such as extreme heat and/or cold.

Such information shall describe:

(a) the study report (including the protocol, acceptance criteria);

(b) the method used for simulated conditions;

(c) the conclusion and recommended shipping conditions.

6.4 Software verification and validation

The documentation shall contain evidence of the validation of the software, as used in the finished device. This information shall typically include the summary results of all verification, validation and testing performed in-house and as applicable in an actual user environment prior to final release. It shall also address all of the different hardware configurations and, where applicable, operating systems identified in the labelling.

6.5 Additional information in specific cases

(a) In the case of devices placed on the market in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps. In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with respect to packaging, sterilisation and maintenance of sterility. The validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues.

(b) In the case of devices containing tissues, cells and substances of animal, human or microbial origin, information on the origin of such material and on the conditions in which it was collected.

(c) In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications.

(d) If the device is to be connected to other equipment in order to operate as intended, a description of this combination including proof that it conforms to the general safety and performance requirements when connected to any such equipment having regard to the characteristics specified by the manufacturer.

ANNEX III

EU DECLARATION OF CONFORMITY

1. Name, registered trade name or registered trade mark of the manufacturer and, if applicable, his authorised representative, and the address of their registered place of business where they can be contacted and their location be established;

2. A statement that the declaration of conformity is issued under the sole responsibility of the manufacturer;

3. The UDI device identifier as referred to in item (i) of point (a) of Article 22(1) as soon as identification of the device that is covered by the declaration shall be based on a UDI system;

4. Product or trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device that is covered by the declaration (it may include a photograph, where appropriate). Except for the product or trade name, the information allowing identification and traceability may be provided by the device identifier referred to in point 3;

5. Risk class of the device in accordance with the rules set out in Annex VII;

6. A statement that the device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with other relevant Union legislation that make provision for the issuing of a declaration of conformity;

~~7. References to the relevant harmonised standards or CTS used in relation to which conformity is declared;~~ **[Am. 266]**

8. Where applicable, name and identification number of the notified body, description of the conformity assessment procedure performed and identification of the certificate(s) issued;

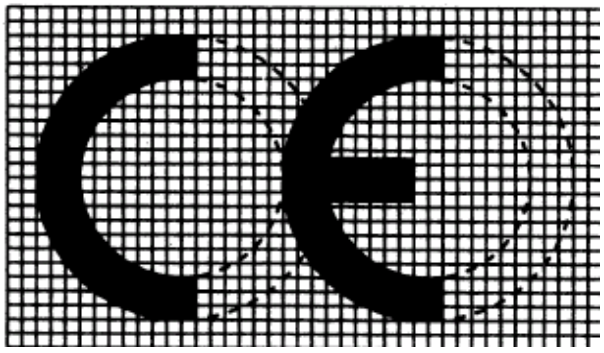
9. Where applicable, additional information;

10. Place and date of issue, name and function of the person who signs as well as indication for and on behalf of whom he/she signs, signature.

ANNEX IV

CE MARKING OF CONFORMITY

1. The CE marking shall consist of the initials ‘CE’ taking the following form:



2. If the CE marking is reduced or enlarged, the proportions given in the above graduated drawing shall be respected.

3. The various components of the CE marking shall have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale devices.

ANNEX V

INFORMATION TO BE SUBMITTED WITH THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLE 23

AND

DATA ELEMENTS OF THE UDI DEVICE IDENTIFIER IN ACCORDANCE WITH ARTICLE 22

Part A

Information to be submitted with the registration of devices in accordance with Article 23

Manufacturers or, when applicable, authorised representatives, and, when applicable, importers shall submit the following information:

1. economic operator's role (manufacturer, authorised representative, or importer),

2. name, address and contact details of the economic operator,

3. where submission of information is completed by another person on behalf of any of the economic operators mentioned under point 1, the name, address and contact details of this person,

4. UDI device identifier, or where identification of the device is not yet based on a UDI system, the data elements laid down in points 5 to 18 of Part B of this Annex,

5. type, number and expiry date of certificate and name or identification number of the notified body that has issued the certificate (and link to the information on the certificate entered by the notified body in the electronic system on certificates),

6. Member State where the device shall or has been placed on the market in the Union,

7. in case of devices classified as classes B, C or D: Member States where the device is or shall be made available,

8. in case of imported device: country of origin,

9. presence of tissues, cells or substances of human origin (y/n),

10. presence of tissues, cells or substances of animal origin (y/n),

11. presence of cells or substances of microbial origin (y/n),

12. risk class of the device according to the rules set out in Annex VII,

13. where applicable, single identification number of the interventional clinical performance study and other clinical performance study involving risks for the subjects of the study conducted in relation to the device (or link to the clinical performance study registration in the electronic system regarding clinical performance studies),

14. in case of devices designed and manufactured by another legal or natural person as referred in Article 8(10), the name, address and contact details of that legal or natural person,

15. in case of devices classified as class C or D, the summary of safety and performance, ***and the full dataset collected during the clinical study and the post-market clinical follow-up,*** **[Am. 216]**

16. status of the device (on the market, no longer manufactured, withdrawn from the market, recalled),

17. indication when the device is a 'new' device.

A device shall be considered as 'new' if:

(a) there has been no such device continuously available on the Union market during the previous three years for the relevant analyte or other parameter;

(b) the procedure involves analytical technology not continuously used in connection with a given analyte or other parameter on the Union market during the previous three years.

18. Indication if the device is intended for self-testing or near-patient testing.

18a. Full technical documentation and the clinical performance report. **[Am. 217]**

Part B

Data elements of the UDI device identifier in accordance with Article 22

The UDI device identifier shall provide access to the following information related to the manufacturer and the device model:

1. quantity per package configuration,

2. if applicable, alternative or additional identifier(s),
3. the way how the device production is controlled (expiration date or manufacturing date, lot or batch number, serialisation number),
4. if applicable, the 'unit of use' device identifier (when a UDI is not assigned to the device at the level of its 'unit of use', a 'unit of use' device identifier shall be assigned to associate the use of a device with a patient),
5. name and address of the manufacturer (as indicated on the label),
6. if applicable, name and address of the authorised representative (as indicated on the label),
7. Global Medical Device Nomenclature (GMDN) code or internationally recognised nomenclature code,
8. if applicable, trade/brand name,
9. if applicable, device model, reference, or catalogue number,
10. additional product description (optional),

11. if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use),
12. if applicable, additional trade names of the device,
13. labelled as single use device (y/n),
14. if applicable, restricted number of reuses,
15. device packaged sterile (y/n),
16. need for sterilisation before use (y/n),
17. URL for additional information, e.g. electronic instructions for use (optional),
18. if applicable, critical warnings or contraindications.

ANNEX VI

MINIMUM REQUIREMENTS TO BE MET BY NOTIFIED BODIES

1. ORGANISATIONAL AND GENERAL REQUIREMENTS

1.1. Legal status and organisational structure

1.1.1. A notified body shall be established under the national law of a Member State, or under the law of a third country with which the Union has concluded an agreement in this respect, and shall have full documentation of its legal personality and status. This shall include information about ownership and the legal or natural persons exercising control over the notified body.

1.1.2. If the notified body is a legal entity that is part of a larger organisation, the activities of this organisation as well as its organisational structure and governance, and the relationship with the notified body shall be clearly documented.

1.1.3. If the notified body wholly or partly owns legal entities established in a Member State or in a third country, the activities and responsibilities of those entities, as well as their legal and operational relationships with the notified body, shall be clearly defined and documented.

1.1.4. The organisational structure, distribution of responsibilities and operation of the notified body shall be such that it assures confidence in the performance and results of the conformity assessment activities conducted.

The organisational structure and the functions, responsibilities and authority of its top-level management and of other personnel with influence upon the performance and results of the conformity assessment activities shall be clearly documented. ***This information shall be made publicly available.***

1.2. Independence and impartiality

1.2.1. The notified body shall be a third-party body that is independent of the manufacturer of the product in relation to which it performs conformity assessment activities. The notified body shall also be independent of any other economic operator having an interest in the product as well as of any competitor of the manufacturer. ***This does not preclude the notified body from performing conformity assessment activities for different economic operators producing different or similar products.***

1.2.2. The notified body shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities. The notified body shall have procedures in place that effectively ensure identification, investigation and resolution of any case in which a conflict of interests may arise, including involvement in consultancy services in the field of *in vitro* diagnostic medical devices prior to taking up employment with the notified body.

1.2.3. The notified body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not

- be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products, nor the authorised representative of any of those parties. This shall not preclude the purchase and use of assessed products that are necessary for the operations of the notified body (e.g. measuring equipment), the conduct of the conformity assessment or the use of such products for personal purposes;
- be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of the products which they assess, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified;

– offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, his authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of the products or processes under assessment. This does not preclude general training activities relating to medical device regulations or related standards that are not client specific.

The notified body shall make publicly available the declarations of interest of its top-level management and the personnel responsible for carrying out the conformity assessment tasks. The national authority shall verify the compliance of the notified body with the provisions under this point and shall report to the Commission twice a year in full transparency.

1.2.4. The impartiality of the notified bodies, of their top level management ~~and~~ **,** of the assessment personnel ***and subcontractors*** shall be guaranteed. The remuneration of the top level management ~~and~~**,** assessment personnel ***and subcontractors*** of a notified body shall not depend on the results of the assessments.

1.2.5. If a notified body is owned by a public entity or institution, independence and absence of any conflict of interests shall be ensured and documented between, on the one hand, the national authority responsible for notified bodies and/or competent authority and, on the other hand, the notified body.

1.2.6. The notified body shall ensure and document that the activities of its subsidiaries or subcontractors, or of any associated body, do not affect its independence, impartiality or objectivity of its conformity assessment activities. ***The notified body shall provide evidence to the national authority of compliance with this point.***

1.2.7. The notified body shall operate in accordance with a set of consistent, fair and reasonable terms and conditions, taking into account the interests of small and medium-sized enterprises as defined by Recommendation 2003/361/EC.

1.2.8. The requirements of this section in no way preclude exchanges of technical information and regulatory guidance between a notified body and a manufacturer seeking their conformity assessment.

1.3. Confidentiality

The personnel of a notified body shall observe professional secrecy with regard to information obtained in carrying out their tasks under this Regulation, ***only in justified cases and*** except in relation to the national authorities responsible for notified bodies, competent authorities or the Commission. Proprietary rights shall be protected. To this end, the notified body shall have documented procedures in place.

Where information and data are requested from the notified body by public or healthcare professionals and where such a request is declined, the notified body shall justify the reasons for non-disclosure and shall make publicly available its justification.

1.4. Liability

The notified body shall take out appropriate liability insurance that corresponds to the conformity assessment activities for which it is notified, including the possible suspension, restriction or withdrawal of certificates, and the geographic scope of its activities, unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

1.5. Financial requirements

The notified body***, including its subsidiaries,*** shall have at its disposal the financial resources required to conduct its conformity assessment activities and related business operations. It shall document and provide evidence of its financial capacity and its sustainable economic viability, taking into account specific circumstances during an initial start-up phase.

1.6. Participation in coordination activities

1.6.1. The notified body shall participate in, or ensure that its assessment personnel ***including subcontractors,*** is informed of ***and trained on*** the relevant standardisation activities and the activities of the notified body coordination group and that its assessment and decision making personnel are informed of all relevant legislation, ***standards***, guidance and best practice documents adopted in the framework of this Regulation. ***The notified body shall keep a record of the actions it takes to inform its personnel.*** **[Am. 218]**

1.6.2. The notified body shall adhere to a code of conduct, addressing among other things, ethical business practices for notified bodies in the field of *in vitro* diagnostic medical devices that is accepted by the national authorities responsible for notified bodies. The code of conduct shall provide for a mechanism of monitoring and verification of its implementation by notified bodies.

2. QUALITY MANAGEMENT REQUIREMENTS

2.1. The notified body shall establish, document, implement, maintain and operate a quality management system that is appropriate to the nature, area and scale of its conformity assessment activities and capable of supporting and demonstrating the consistent achievement of the requirements of this Regulation.

2.2. The quality management system of the notified body ***and its subcontractors*** shall at least address the following:

- policies for assignment of personnel to activities and their responsibilities;
- decision-making process in accordance with the tasks, responsibilities and role of the top-level management and other notified body personnel;
- control of documents;
- control of records;
- management review;
- internal audits;

– corrective and preventive actions;

– complaints and appeals;

– ***continuous training.*** **[Am. 219]**

3. RESOURCE REQUIREMENTS

3.1. General

3.1.1. A notified body ***and its subcontractors*** shall be capable of carrying out all the tasks assigned to it by this Regulation with the highest degree of professional integrity and the requisite technical competence in the specific field, whether those tasks are carried out by the notified body itself or on its behalf and under its responsibility. ***In accordance with Article 35, this requirement shall be monitored to ensure that it is of the requisite quality.***

In particular, it shall have the necessary personnel and shall possess or have access to all equipment and facilities needed to perform properly the technical***, scientific*** and administrative tasks entailed in the conformity assessment activities in relation to which it has been notified.

This presupposes the ***permanent*** availability within its organisation of sufficient scientific personnel who possess experience***, a university degree*** and ***the*** knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified, having regard to the requirements of this Regulation and, in particular, those set out in Annex I.

Permanent "in-house" staff shall be used. However, in accordance with Article 30, notified bodies may hire external experts on an ad hoc and temporary basis provided they can make publicly available the list of those experts, as well as their declarations of interest and the specific tasks for which they are responsible.

Notified bodies shall conduct unannounced inspections at least once a year of all premises at which the medical devices coming within their remit are manufactured.

The notified body responsible for carrying out the assessment tasks shall notify the other Member States of the findings of the annual inspections carried out. Those findings shall be set out in a report.

It shall also forward a record of the annual inspections carried out to the relevant national authority responsible.

3.1.2. At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a notified body shall have within its organisation the necessary administrative, technical and scientific personnel with ***medical,*** technical ***and where needed pharmacological*** knowledge and sufficient and appropriate experience relating to in vitro diagnostic medical devices and the corresponding technologies to perform the conformity assessment tasks, including the assessment of clinical data ***or the evaluation of an assessment made by a subcontractor***.

3.1.3. The notified body shall clearly document the extent and the limits of the duties, responsibilities and authorities in relation of the personnel***, including any subcontractors, subsidiaries and external experts***, involved in conformity assessment activities and inform the personnel concerned about it.

3.1.3a. The notified body shall make available the list of its personnel involved in conformity assessment activities and their expertise to the Commission and, upon request, to other parties. That list shall be kept up to date. **[Am. 220]**

3.2. Qualification criteria in relation to personnel

3.2.1. The ***MDCG*** shall establish and document ***the principles of high level competence and*** qualification criteria and procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing training). The qualification criteria shall address the various functions within the conformity assessment process (e.g. auditing, product evaluation/testing, design dossier/file review, decision-making) as well as the devices, technologies and areas covered by the scope of designation.

3.2.2. The qualification criteria shall refer to the scope of the notified body's designation in accordance with the scope description used by the Member State for the notification referred to in Article 31, providing sufficient level of detail for the required qualification within the subdivisions of the scope description.

Specific qualification criteria shall be defined for the assessment of biocompatibility aspects, ***safety,*** clinical evaluation and the different types of sterilisation processes.

3.2.3. The personnel responsible for authorising other personnel to perform specific conformity assessment activities and the personnel with overall responsibility for the final review and decision-making on certification shall be employed by the notified body itself and shall not be subcontracted. This personnel altogether shall have proven knowledge and experience in the following:

– Union *in vitro* diagnostic medical devices legislation and relevant guidance documents;

– the conformity assessment procedures in accordance with this Regulation;

– a broad base of *in vitro* diagnostic medical device technologies, the *in vitro* diagnostic medical device industry and the design and manufacture of *in vitro* diagnostic medical devices;

– the notified body's quality management system and related procedures;

– the types of qualifications (knowledge, experience and other competence) required for carrying out conformity assessments in relation to *in vitro* diagnostic medical devices as well as the relevant qualification criteria;

– training relevant to personnel involved in conformity assessment activities in relation to *in vitro* diagnostic medical devices;

– the ability to draw up certificates, records and reports demonstrating that the conformity assessments have been appropriately carried out;

– ***at least three years' appropriate experience in the field of conformity assessments within a notified body,***

– ***adequate seniority / experience in conformity assessments under this Regulation or previously applicable law during a period of at least three years within a notified body. The notified body staff involved in certification decisions shall not have been involved in the conformity assessment on which a certification decision needs to be taken.***

3.2.4. ***Clinical experts*****:** notified bodies shall have available personnel with ~~clinical~~ expertise ***in clinical investigation design, medical statistics, clinical patient management, good clinical practice in the field of clinical investigations. Permanent "in-house" staff shall be used. However, in accordance with Article 28, notified bodies may hire external experts on an ad hoc and temporary basis provided they can make publicly available the list of those experts, as well as the specific tasks for which they are responsible.*** This personnel shall be integrated in the notified body's decision-making process in a steady way in order to:

– identify when specialist input is required for the assessment of ***the clinical investigation plans and*** the clinical evaluation conducted by the manufacturer and identify appropriately qualified experts;

– appropriately train external clinical experts in the relevant requirements of this Regulation, delegated and/or implementing acts, harmonised standards, CTS and guidance documents and ensure that the external clinical experts are fully aware of the context and implication of their assessment and advice provided;

– be able to discuss ~~the clinical data contained within the manufacturer's clinical evaluation~~ ***the rationale of the planned study design, the clinical investigation plans and the selection of the control intervention*** with the manufacturer and with external clinical experts and to appropriately guide external clinical experts in the assessment of the clinical evaluation;

– be able to scientifically challenge ***the clinical investigation plans and*** the clinical data presented, and the results of the external clinical experts' assessment of the manufacturer's clinical evaluation;

– be able to ascertain the comparability and consistency of the clinical assessments conducted by clinical experts;

– be able to make an objective clinical judgement about the assessment of the manufacturer's clinical evaluation and make a recommendation to the notified body's decision maker;

– ***ensure independence and objectivity and disclose potential conflicts of interest.***

3.2.5. ***Product assessors:*** the personnel responsible for carrying out product related ~~review~~ ***reviews*** (e.g. design dossier review, technical documentation review or type examination including aspects such as clinical evaluation, sterilisation, software validation) shall have ~~the following proven qualification~~ ***specialist qualifications which should include***:

– successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, natural science or engineering;

– four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the design, manufacture, testing or use of the device ***(as defined within a generic device group)*** or technology to be assessed or related to the scientific aspects to be assessed;

– appropriate knowledge of the general safety and performance requirements laid down in Annex I as well as related delegated and/or implementing acts, harmonised standards, CTS and guidance documents;

- ***a qualification based on technical or scientific fields (e.g. sterilization, biocompatibility, animal tissue, human tissue, software, functional safety, clinical evaluation, electrical safety, packaging);***

– appropriate knowledge and experience of risk management and related *in vitro* diagnostic medical device standards and guidance documents;

– ***appropriate knowledge and experience of clinical evaluation;***

– appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes VIII to X, in particular of those aspects for which they are authorised, and adequate authority to carry out those assessments.

3.2.6. ***Auditor:*** The personnel responsible for carrying out audits of the manufacturer's quality ~~management~~ ***assurance*** system shall have ~~the following proven qualification~~ ***specialist qualifications, which should include***:

– successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, natural sciences or engineering;

– four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the area of quality management;

– ***appropriate knowledge of technologies such as those defined by IAF/EAC coding or equivalent;*** **[Am. 221]**

– appropriate knowledge of the *in vitro* diagnostic medical devices legislation as well as related delegated and/or implementing acts, harmonised standards, CTS and guidance documents;

– appropriate knowledge and experience of risk management and related *in vitro* diagnostic medical device standards and guidance documents;

– appropriate knowledge of quality management systems and related standards and guidance documents;

– appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes VIII to X, in particular of those aspects for which they are authorised, and adequate authority to carry out the audits;

– training in auditing techniques enabling them to challenge quality management systems.

3.3. Documentation of qualification, training and authorisation of personnel

3.3.1. The notified body shall have a process in place to fully document the qualification of each personnel involved in conformity assessment activities and the satisfaction of the qualification criteria referred to in Section 3.2. Where in exceptional circumstances the fulfilment of the qualification criteria set out in Section 3.2 cannot be fully demonstrated, the notified body shall appropriately justify the authorisation of this personnel to carry out specific conformity assessment activities.

3.3.2. For its personnel referred to in Sections 3.2.3 to 3.2.6, the notified body shall establish and maintain up to date:

- a matrix detailing the responsibilities of the personnel in respect of the conformity assessment activities;
- records demonstrating the required knowledge and experience for the conformity assessment activity for which they are authorised.

3.4. Subcontractors and external experts

3.4.1. Without prejudice to the limitations emanating from Section 3.2., the notified bodies may subcontract clearly defined parts of the conformity assessment activities ***in particular where clinical expertise is limited***. The subcontracting of the auditing of quality management systems or of product related reviews as a whole is not allowed.

3.4.2. Where a notified body subcontracts conformity assessment activities either to an organisation or an individual, it shall have a policy describing the conditions under which subcontracting may take place. Any subcontracting or consultation of external experts shall be properly documented***, be publicly available*** and be subject to a written agreement covering, among others, confidentiality and conflict of interests.

3.4.3. Where subcontractors or external experts are used in the context of the conformity assessment, the notified body shall have adequate own competence in each product area **,** ***each treatment or medical speciality*** for which it is designated to lead the conformity assessment, to verify the appropriateness and validity of expert opinions and make the decision on the certification.

3.4.4. The notified body shall establish procedures for assessing and monitoring the competence of all subcontractors and external experts used.

3.4.4a. The policy and procedures under points 3.4.2 and 3.4.4 shall be communicated to the national authority before any subcontracting takes place. **[Am. 222]**

3.5. Monitoring of competences and training

3.5.1. The notified body shall appropriately monitor the satisfactory performance of the conformity assessment activities by its personnel.

3.5.2. It shall review the competence of its personnel and identify training needs ***and ensure that necessary measures are taken accordingly,*** in order to maintain the required level of qualification and knowledge. **[Am. 223]**

3.5a. Additional requirements for special notified bodies

3.5a.1. Clinical Experts for special notified bodies

Notified bodies shall have available personnel with expertise in clinical investigation design, medical statistics, clinical patient management, good clinical practice in the field of clinical investigations and pharmacology. Permanent "in-house" staff shall be used. However, in accordance with Article 30, notified bodies may hire external experts on an ad hoc and temporary basis provided they can make publicly available the list of those experts, as well as the specific tasks for which they are responsible. That personnel shall be integrated in the notified body's decision-making process in a steady way in order to:

- ***identify when specialist input is required for the assessment of the clinical investigation plans and the clinical evaluation conducted by the manufacturer and identify appropriately qualified experts;***
- ***appropriately train external clinical experts in the relevant requirements of this Regulation, delegated and/or implementing acts, harmonised standards, CTS and guidance documents and ensure that the external clinical experts are fully aware of the context and implication of their assessment and advice provided;***
- ***be able to discuss the rationale of the planned study design, the clinical investigation plans and the selection of the control intervention with the manufacturer and with external clinical experts and to appropriately guide external clinical experts in the assessment of the clinical evaluation;***
- ***be able to scientifically challenge the clinical investigation plans and the clinical data presented, and the results of the external clinical experts' assessment of the manufacturer's clinical evaluation;***
- ***be able to ascertain the comparability and consistency of the clinical assessments conducted by clinical experts;***

- ***be able to make an objective clinical judgement about the assessment of the manufacturer's clinical evaluation and make a recommendation to the notified body's decision maker;***
- ***have an understanding of active substances;***
- ***ensure independence and objectivity and disclose potential conflicts of interest.*** **[Am. 224]**

3.5a.2. Product specialists for special notified bodies

The personnel responsible for carrying out product related reviews (e.g. design dossier review, technical documentation review or type examination) for devices referred to in Article 41a shall have the following proven product specialist qualifications:

- ***meet the requirement for product assessors;***
- ***have an advanced academic degree in a field relevant to medical devices, or alternatively have six years of relevant experience in in vitro diagnostic medical devices or related sectors;***
- ***have an ability to identify key risks of products within the specialist’s product categories without prior reference to manufacturer’s specifications or risk analyses;***

- ***have an ability to assess the essential requirements in the absence of harmonised or established national standards;***
- ***the professional experience should be gained in the first product category their qualification is based on, relevant to the product category of designation of the notified body, providing sufficient knowledge and experience to thoroughly analyse the design, the validation and verification testing and the clinical use , with a sound understanding of the design, manufacture, testing, clinical use and risks associated with such a device;***
- ***missing professional experience for further product categories closely related to the first product category, may be substituted by internal product specific training programmes;***
- ***for product specialists with qualifications in specific technology, professional experience should be gained in the specific technology area, relevant to the scope of designation of the notified body.***

For each designated product category, the special notified body shall have a minimum of two product specialists of which at least one in-house, to review devices referred to in Article 41a(1). For those devices, product specialists shall be available in-house for the designated technology fields covered by the scope of notification. **[Am. 267]**

3.5a.3. Training for product specialists

Product specialists shall receive a minimum of 36 hours of training in in vitro diagnostic medical devices, in vitro diagnostic medical device regulations, and assessment and certification principles, including training in the verification of manufactured product.

The notified body shall ensure that in order for a product specialist to be qualified, he or she obtains adequate training in the relevant procedures of the notified body's quality management system and is taken through a training plan consisting of sufficient design dossier reviews witnessed, performed under supervision and peer reviewed before doing a qualifying full independent review.

For each product category for which qualification is sought, the notified body must show evidence of appropriate knowledge in the product category. A minimum of five design dossiers (at least two of them initial applications or significant extensions of certification) shall be conducted for the first product category. For subsequent qualification in additional product categories evidence of adequate product knowledge and experience needs to be demonstrated. **[Am. 226]**

3.5a.4. Maintenance qualification for product specialists

Qualifications of product specialists shall be reviewed on an annual basis; a minimum of four design dossier reviews, independent of the number of product categories qualified for shall be demonstrated as a four-year rolling average. Reviews of significant changes to the approved design (not full design examinations) shall count for 50%, as shall reviews supervised.

On an ongoing basis, the product specialist shall be required to show evidence of state-of-the-art product knowledge, review experience in each product category for which qualification exists. Annual training with regard to latest status of Regulations, harmonized standards, relevant guidance documents, clinical evaluation, performance evaluation, CTS requirements must be demonstrated.

If the requirements for renewal of qualification are not met, the qualification shall be suspended. Then the first upcoming design dossier review shall be done under supervision, and re-qualification confirmed based on the outcome of that review.
[Am. 227]

4. PROCESS REQUIREMENTS

4.1. The notified body's decision-making process shall be ***transparent and*** clearly documented ***and its outcome publicly available***, including the ~~process for the~~ issue, suspension, reinstatement, withdrawal or refusal of conformity assessment certificates, their modification or restriction and the issue of supplements.

4.2. The notified body shall have in place a documented process for the conduct of the conformity assessment procedures for which it is designated taking into account their respective specificities, including legally required consultations, in respect of the different categories of devices covered by the scope of notification, ensuring transparency and the ability of reproduction of those procedures.

4.3. The notified body shall have in place documented procedures ***that are publicly available*** covering at least:

– the application for conformity assessment by a manufacturer or by an authorised representative,

– the processing of the application, including the verification of the completeness of the documentation, the qualification of the product as in vitro diagnostic medical device and its classification, ***as well as the recommended duration for conducting its conformity assessment,*** **[Am. 228]**

– the language of the application, of the correspondence and of the documentation to be submitted,

– the terms of the agreement with the manufacturer or authorised representative,

– the fees to be charged for conformity assessment activities,

– the assessment of relevant changes to be submitted for prior approval,

– the planning of surveillance,

– the renewal of certificates.

4a. A RECOMMENDED DURATION FOR CONFORMITY ASSESSMENTS CONDUCTED BY NOTIFIED BODIES

4.1. Notified bodies shall identify the audit duration for the stage 1 and stage 2 initial audits, and surveillance audits for each applicant and certified client.

4.2. An audit duration shall be based, inter alia, on the effective number of personnel of the organisation, the complexity of the processes within the organisation, the nature and the characteristics of the medical devices included in the scope of the audit and the different technologies that are employed to manufacture and control the medical devices. The audit duration may be adjusted based on any significant factors that uniquely apply to the organisation to be audited. The notified body shall ensure that any variation in audit duration does not compromise the effectiveness of audits.

4.3. The duration of any scheduled on site audit shall not be less than one auditor/day.

4.4. Certification of multiple sites under one quality assurance system shall not be based on a sampling system. **[Am. 229]**

ANNEX VII

CLASSIFICATION CRITERIA

1. IMPLEMENTING RULES FOR THE CLASSIFICATION RULES

1.1. Application of the classification rules shall be governed by the intended purpose***, novelty, complexity and inherent risk*** of the devices. **[Am. 230]**

1.2. If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices.

1.3. Accessories are classified in their own right separately from the device with which they are used.

1.4. Standalone software, which drives a device or influences the use of a device, falls automatically in the same class as the device. If standalone software is independent of any other device, it is classified in its own right.

1.5. Calibrators intended to be used with a device shall be classified in the same class as the device.

1.6. Standalone control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes shall be classified in the same class as the device.

1.7. The manufacturer shall take into consideration all the rules in order to establish the proper classification for the device.

1.8. Where a device has multiple intended purposes stated by the manufacturer, which place the device into more than one class, it shall be classified in the higher class.

1.9. If several classification rules apply to the same device the rule resulting in the higher classification shall apply.

2. CLASSIFICATION RULES

2.1. Rule 1

Devices intended for the following purposes are classified as **class D**:

- Devices intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, cells, tissues or organs, or in any of their derivatives, in order to assess their suitability for transfusion or transplantation.
- Devices intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening disease with a high or currently undefined risk of propagation.

This rule applies to first line assays, confirmatory assays and supplemental assays.

2.2. Rule 2

Devices intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation, are classified as **class C,** except when intended to determine any of the following markers:

- ABO system [A (ABO1), B (ABO2), AB (ABO3)];
- Rhesus system [RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e)];
- Kell system [Kel1 (K)];
- Kidd system [JK1 (Jka), JK2 (Jkb)];
- Duffy system [FY1 (Fya), FY2 (Fyb)]

in which case they are classified as **class D.**

2.3. Rule 3

Devices are classified as **class C** if they are intended for:

(a) detecting the presence of, or exposure to, a sexually transmitted agent;

(b) detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation;

(c) detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual or foetus ***or embryo*** being tested, or to the individual's offspring; **[Am. 231]**

(d) pre-natal screening of women in order to determine their immune status towards transmissible agents;

(e) determining infective disease status or immune status, if there is a risk that an erroneous result would lead to a patient management decision resulting in an imminent life-threatening situation for the patient or for the patient's offspring;

(f) selection of patients, *i.e.*

(i) Devices intended to be used as companion diagnostics; or

(ii) Devices intended to be used for disease staging ***or prognosis***; or **[Am. 232]**

(iii) Devices intended to be used in screening for or in the diagnosis of cancer.

(g) human genetic testing;

(h) monitoring of levels of medicinal products, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient or for the patient's offspring;

(i) management of patients suffering from a life-threatening infectious disease;

(j) screening for congenital disorders in the foetus ***or embryo***. **[Am. 233]**

2.4. Rule 4

(a) Devices intended for self-testing are classified as class C, except those devices from which the result is not determining a medically critical status, or is preliminary and requires follow-up with the appropriate laboratory test in which case they are Class B.

(b) Devices intended for blood gases and blood glucose determinations for near-patient testing are class C. Other devices that are intended for near-patient testing shall be classified in their own right.

2.5. Rule 5

The following devices are classified as **class A**:

(a) reagents or other articles which possess specific characteristics, intended by the manufacturer to make them suitable for *in vitro* diagnostic procedures related to a specific examination;

(b) instruments intended by the manufacturer specifically to be used for *in vitro* diagnostic procedures;

(c) specimen receptacles.

2.6. Rule 6

Devices not covered by the above-mentioned classification rules are classified as **class B**.

2.7. Rule 7

Devices which are controls without a quantitative or qualitative assigned value are classified as **class B**.

ANNEX VIII

CONFORMITY ASSESSMENT BASED ON FULL QUALITY ASSURANCE AND DESIGN EXAMINATION

Chapter I: Full Quality Assurance System

1. The manufacturer shall ensure application of the quality management system approved for the design, manufacture and final inspection of the devices concerned, as specified in Section 3, and is subject to audit as laid down in Sections 3.3 and 3.4 and to the surveillance as specified in Section 4.

2. The manufacturer who fulfils the obligations imposed by Section 1 shall draw up and keep an EU declaration of conformity in accordance with Article 15 and Annex III for the device model covered by the conformity assessment procedure. By issuing a declaration of conformity, the manufacturer ensures and declares that the devices concerned meet the provisions of this Regulation which apply to them.

3. Quality management system

3.1. The manufacturer shall lodge an application for assessment of his quality management system with a notified body. The application shall include:

- the name and address of the manufacturer and any additional manufacturing site covered by the quality management system, and, if the application is lodged by the authorised representative, his name and address as well,
- all the relevant information on the device or device category covered by the procedure,
- a written declaration that no application has been lodged with any other notified body for the same device-related quality management system, or information about any previous application for the same device-related quality management system that has been refused by another notified body,
- the documentation on the quality management system,
- a description of the procedures in place to fulfil the obligations imposed by the quality management system approved and the undertaking by the manufacturer to apply these procedures,
- a description of the procedures in place to keep the approved quality management system adequate and efficacious and an undertaking by the manufacturer to apply these procedures,

– the documentation on the post-market surveillance plan, including, when applicable, a plan for the post-market follow-up, and the procedures put in place to ensure compliance with the obligations emanating from the provisions on vigilance set out in Articles 59 to 64,

– a description of the procedures in place to keep up to date the post-market surveillance plan, including, when applicable, a plan for the post-market follow-up, and the procedures ensuring compliance with the obligations emanating from the provisions on vigilance set out in Articles 59 to 64, as well as the undertaking by the manufacturer to apply these procedures.

3.2. Application of the quality management system shall ensure that the devices conform to the provisions of this Regulation which apply to them at every stage, from design to final inspection. All the elements, requirements and provisions adopted by the manufacturer for his quality management system shall be documented in a systematic and orderly manner in the form of written policies and procedures, such as quality programmes, quality plans, quality manuals and quality records.

Moreover, the documentation to be submitted for the assessment of the quality management system shall include an adequate description of, in particular:

(a) the manufacturer's quality objectives;

(b) the organisation of the business and in particular:

- the organisational structures, the responsibilities of the managerial staff and their organisational authority where quality of design and manufacture of the products is concerned,
- the methods of monitoring the efficient operation of the quality management system and in particular its ability to achieve the desired quality of design and of product, including control of products which fail to conform,
- where the design, manufacture and/or final inspection and testing of the products, or elements thereof, is carried out by another party, the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the other party,
- where the manufacturer does not have a registered place of business in a Member State, the draft mandate for the designation of an authorised representative and a letter of intention of the authorised representative to accept the mandate;

(c) the procedures and techniques for monitoring, verifying, validating and controlling the design of the devices, including the corresponding documentation as well as the data and records arising from those procedures and techniques;

(d) the inspection and quality assurance techniques at the manufacturing stage and in particular:

– the processes and procedures which will be used, particularly as regards sterilisation, purchasing and the relevant documents,

– the product identification ***and traceability*** procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture; **[Am. 235]**

(e) the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it shall be possible to trace back the calibration of the test equipment adequately.

In addition, the manufacturer shall grant the notified body access to the technical documentation referred to in Annex II.

3.3. Audit

(a) The notified body shall audit the quality system to determine whether it meets the requirements referred to in Section 3.2. Unless duly substantiated, it shall presume that quality management systems which satisfy the relevant harmonised standards or CTS conform to the requirements covered by the standards or CTS.

(b) The assessment team shall include at least one member with past experience of assessments of the technology concerned. The assessment procedure shall include an audit on the manufacturer's premises and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing and other relevant processes.

(c) Moreover, in the case of devices classified as class C, the audit procedure shall include an assessment, on a representative basis, of the design documentation within the technical documentation as referred to in Annex II of the device(s) concerned. In choosing representative sample(s) the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended purpose and the results of any previous relevant assessments that have been carried out in accordance with this Regulation. The notified body shall document its rationale for the sample(s) taken.

(d) If the quality management system conforms to the relevant provisions of this Regulation, the notified body shall issue an EU full quality assurance certificate. The decision shall be notified to the manufacturer. It shall contain the conclusions of the audit and a reasoned assessment.

3.4. The manufacturer shall inform the notified body which approved the quality management system of any plan for substantial changes to the quality management system or the product-range covered. The notified body shall assess the changes proposed and verify whether after these changes the quality management system still meets the requirements referred to in Section 3.2. It shall notify the manufacturer of its decision which shall contain the conclusions of the audit and a reasoned assessment. The approval of any substantial change to the quality management system or the product-range covered shall take the form of a supplement to the EU full quality assurance certificate.

4. Surveillance assessment applicable to devices classified as class C and D

4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality management system.

4.2. The manufacturer shall authorise the notified body to carry out all the necessary audits, including inspections, and supply it with all relevant information, in particular:

- the documentation on the quality management system,
- the documentation on the post-market surveillance plan, including a post-market follow-up, as well as, if applicable, any findings resulting from the application of the post-market surveillance plan, including the post-market follow-up, and of the provisions on vigilance set out in Articles 59 to 64,
- the data stipulated in the part of the quality management system relating to design, such as the results of analyses, calculations, tests and the solutions adopted regarding the risk-management as referred to in Section 2 of Annex I,
- the data stipulated in the part of the quality management system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3. The notified body shall periodically, at least every 12 months, carry out appropriate audits and assessments to make sure that the manufacturer applies the approved quality management system and the post-market surveillance plan, and shall supply the manufacturer with an assessment report. This shall include inspections on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors. At the time of such inspections, the notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

4.4. The notified body shall randomly perform ***for each manufacturer and generic device group*** unannounced ~~factory~~ inspections ~~to the manufacturer~~ ***at the relevant manufacturing sites*** and, if appropriate, ~~of~~ the manufacturer's suppliers and/or subcontractors ~~which may be combined with the periodic surveillance assessment referred to in Section 4.3. or be performed in addition to this surveillance assessment~~. The notified body shall establish a plan for the unannounced inspections which shall not be disclosed to the manufacturer. ***At the time of such inspections, the notified body shall carry out tests or ask to carry them out in order to check that the quality management system is working properly. It shall provide the manufacturer with an inspection report and with a test report. The notified body shall carry out such inspections at least once every three years.*** **[Am. 236]**

Within the context of such unannounced inspections, the notified body shall check an adequate sample from the production or the manufacturing process to verify that the manufactured device is in conformity with the technical documentation and/or design dossier. Prior to the unannounced inspection, the notified body shall specify the relevant sampling criteria and testing procedure.

Instead of, or in addition to, the sampling from the production, the notified body shall take samples of devices from the market to verify that the manufactured device is in conformity with the technical documentation and/or design dossier. Prior to the sampling, the notified body shall specify the relevant sampling criteria and testing procedure.

The notified body shall provide the manufacturer with an inspection report which shall include, if applicable, the result of the sample check.

4.5. In the case of devices classified as class C, the surveillance assessment shall also include the assessment of the design documentation within the technical documentation of the device(s) concerned on the basis of further representative sample(s) chosen in accordance with the rationale documented by the notified body in accordance with point (c) of Section 3.3.

4.6. The notified body shall ensure that the composition of the assessment team assures experience with the technology concerned, continuous objectivity and neutrality; this shall include a rotation of the members of the assessment team at appropriate intervals. As a general rule, a lead auditor shall not lead and attend an audit for more than three consecutive years in respect to the same manufacturer.

4.7. If the notified body establishes a divergence between the sample taken from the production or from the market and the specifications laid down in the technical documentation or the approved design, it shall suspend or withdraw the relevant certificate or impose restrictions on it.

Chapter II: Design dossier examination

5. Examination of the design of the device and batch verification applicable to devices in class D

5.1. In addition to the obligation imposed by Section 3, the manufacturer of devices classified as class D shall lodge with the notified body referred to in Section 3.1 an application for the examination of the design dossier relating to the device which he plans to manufacture and which falls into the device category covered by the quality management system referred to in Section 3.

5.2. The application shall describe the design, manufacture and performances of the device in question. It shall include the technical documentation as referred to in Annex II; where the technical documentation is voluminous and/or held in different locations, the manufacturer shall submit a summary technical documentation (STED) and grant access to the full technical documentation upon request.

In the case of devices for self-testing or near-patient testing, the application shall also include the aspects referred to in Section 6.1, point b).

5.3. The notified body shall examine the application employing staff with proven knowledge and experience regarding the technology concerned. ***The notified body shall ensure that the manufacturer's application adequately describes the design, manufacture and performance of the device, allowing assessment of whether the product conforms with the requirements set out in this Regulation. The notified body shall comment on the conformity of the following:***

- ***general description of the product,***
- ***design specifications, including a description of the solutions adopted to fulfil the essential requirements,***
- ***systematic procedures used for the design process and techniques used to control, monitor and verify the design of the device.*** **[Am. 237]**

The notified body may require the application to be completed by further tests or other evidence to allow assessment of conformity with the requirements of this Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.

5.4. Before issuing an EU design-examination certificate, the notified body shall request a reference laboratory, where designated in accordance with Article 78, to verify compliance of the device with the CTS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent.

The reference laboratory shall provide a scientific opinion within 30 days.

The scientific opinion of the reference laboratory and any possible updates shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision. The notified body shall not deliver the certificate if the scientific opinion is unfavourable.

5.5. The notified body shall provide the manufacturer with an EU design-examination report.

If the device conforms to the relevant provisions of this Regulation, the notified body shall issue an EU design-examination certificate. The certificate shall contain the conclusions of the examination, the conditions of validity, the data needed for identification of the approved design, where appropriate, a description of the intended purpose of the device.

5.6. Changes to the approved design shall receive further approval from the notified body which issued the EU design-examination certificate, wherever the changes could affect conformity with the general safety and performance requirements of this Regulation or with the conditions prescribed for use of the device. The applicant shall inform the notified body which issued the EU design-examination certificate of any planned changes to the approved design. The notified body shall examine the planned changes, notify the manufacturer of its decision and provide him with a supplement to the EU design-examination report.

Where the changes could affect compliance with the CTS or with other solutions chosen by the manufacturer which were approved through the EU design-examination certificate, the notified body shall consult the reference laboratory that was involved in the initial consultation, in order to confirm that compliance with the CTS or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent are maintained.

The reference laboratory shall provide a scientific opinion within 30 days.

The approval of any change to the approved design shall take the form of a supplement to the EU design-examination certificate.

5.7. To verify conformity of manufactured devices classified as class D, the manufacturer shall carry out tests on the manufactured devices or each batch of devices. After the conclusion of the controls and tests he shall forward to the notified body without delay the relevant reports on these tests. Furthermore, the manufacturer shall make the samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and modalities which shall include that the notified body or the manufacturer, ~~in regular intervals,~~ shall send samples of the manufactured devices or batches of devices to a reference laboratory, where designated in accordance with Article 78, to carry out appropriate tests. The reference laboratory shall inform the notified body about its findings. **[Am. 238]**

5.8. The manufacturer may place the devices on the market, unless the notified body communicates to the manufacturer within the agreed time-frame, but not later than 30 days after reception of the samples, any other decision, including in particular any condition of validity of delivered certificates.

6. Examination of the design of specific types of devices

6.1. Examination of the design of devices for self-testing ~~and near-patient testing~~ classified as class A, B or C ***and of devices for near patient testing classified as class C*** **[Am. 239]**

(a) The manufacturer of devices for self-testing ~~or near-patient testing~~ classified as class A, B and C ***and of devices for near patient testing classified as class C*** shall lodge with the notified body referred to in Section 3.1 an application for the examination of the design.**[Am. 240]**

(b) The application shall enable the design of the device to be understood and shall enable conformity with the design-related requirements of this Regulation to be assessed. It shall include:

- test reports, including results of studies carried out with intended users;
- where practicable, an example of the device; if required, the device shall be returned on completion of the design examination;
- data showing the handling suitability of the device in view of its intended purpose for self-testing or near patient-testing;
- the information to be provided with the device on its label and its instructions for use.

The notified body may require the application to be completed by further tests or proof to allow assessment of conformity with the requirements of this Regulation.

(c) The notified body shall examine the application employing staff with proven knowledge and experience regarding the technology concerned and provide the manufacturer with an EU design-examination report.

(d) If the device conforms to the relevant provisions of this Regulation, the notified body shall issue an EU design-examination certificate. The certificate shall contain the conclusions of the examination, the conditions of validity, the data needed for the identification of the approved design and, where appropriate, a description of the intended purpose of the device.

(e) Changes to the approved design shall receive further approval from the notified body which issued the EU design-examination certificate, wherever the changes could affect conformity with the general safety and performance requirements of this Regulation or with the conditions prescribed for use of the device. The applicant shall inform the notified body which issued the EU design-examination certificate of any planned changes to the approved design. The notified body shall examine the planned changes, notify the manufacturer of its decision and provide him with a supplement to the EU design-examination report. The approval of any change to the approved design shall take the form of a supplement to the EU design-examination certificate.

6.2. Examination of the design of companion diagnostics

(a) The manufacturer of a companion diagnostic shall lodge with the notified body referred to in Section 3.1 an application for the examination of the design.

(b) The application shall enable the design of the device to be understood and shall enable conformity with the design-related requirements of this Regulation to be assessed, in particular, with regard to the suitability of the device in relation to the medicinal product concerned.

(c) For companion diagnostic intended to be used to assess the patient eligibility to a treatment with a specific medicinal product, the notified body shall consult before issuing an EU design-examination certificate and on the basis of the draft summary of safety and performance and the draft instructions for use, one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC (hereinafter referred to as 'medicinal products competent authority') or the European Medicines Agency (hereinafter referred to as 'EMA') established by the Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1], regarding the suitability of the device in relation to the medicinal product concerned. Where the medicinal product falls exclusively within the scope of the Annex of Regulation (EC) No 726/2004, the notified body shall consult the EMA.

1 OJ L 136, 30.4.2004, p. 1.

(d) The medicinal products competent authority or the EMA shall give its opinion, if any, within 60 days after receipt of valid documentation. This 60-day period may be extended only once for a further 60 days on scientifically valid grounds. The opinion of the medicinal products authority or of the EMA and any possible update shall be included in the documentation of the notified body concerning the device.

(e) The notified body shall give due consideration to the opinion, if any, expressed by the medicinal products competent authority concerned or the EMA ***on the scientific suitability of the companion diagnostic*** when making its decision. ***If the notified body deviates from that position,*** it shall ~~convey its final~~ ***justify its*** decision to the medicinal products competent authority concerned or to the EMA. ***If no agreement is reached, the notified body shall inform the MDCG thereof.*** The design-examination certificate shall be delivered in accordance with point (d) of Section 6.1. **[Am. 241]**

(f) Before changes affecting the suitability of the device in relation to the medicinal product concerned are made, the manufacturer shall inform the notified body of the changes, which shall consult the medicinal products competent authority that was involved in the initial consultation or the EMA. The medicinal products competent authority or the EMA shall give its opinion, if any, within 30 days after receipt of the valid documentation regarding the changes. A supplement to the EU design-examination certificate shall be issued in accordance with point (e) of Section 6.1.

Chapter III: Administrative provisions

7. The manufacturer or his authorised representative shall, for a period ending at least five years after the last device has been placed on the market, keep at the disposal of the competent authorities:

- the declaration of conformity,
- the documentation referred to in the fourth indent of Section 3.1 and in particular the data and records arising from the procedures referred to in point (c) of Section 3.2.,
- the changes referred to in Section 3.4,
- the documentation referred to in Sections 5.2 and point (b) of Section 6.1, and
- the decisions and reports from the notified body as referred to in Sections 3.3, 4.3, 4.4, 5.5, 5.6, 5.8, points (c), (d) and (e) of Section 6.1, point (e) of Section 6.2 and point (f) of Section 6.2.

8. Each Member State shall make provision that this documentation is kept at the disposal of the competent authorities for the period indicated in the first sentence of the preceding paragraph in case the manufacturer, or his authorised representative, established within its territory goes bankrupt or ceases its business activity prior to the end of this period.

ANNEX IX

CONFORMITY ASSESSMENT BASED ON TYPE EXAMINATION

1. EU type-examination is the procedure whereby a notified body ascertains and certifies that a representative sample of the production covered fulfils the relevant provisions of this Regulation.

2. Application

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, the name and address of the authorised representative,
- the technical documentation referred to in Annex II needed to assess the conformity of the representative sample of the production in question, hereinafter referred to as the 'type', with the requirements of this Regulation; where the technical documentation is voluminous and/or held in different locations, the manufacturer shall submit a summary technical documentation (STED) and grant access to the full technical documentation upon request. The applicant shall make a 'type' available to the notified body. The notified body may request other samples as necessary,
- in the case of devices for self-testing or near-patient testing, test reports, including results of studies carried out with intended users, and data showing the handling suitability of the device in view of its intended purpose for self-testing or near patient-testing,

– a written declaration that no application has been lodged with any other notified body for the same type, or information about any previous application for the same type that has been refused by another notified body.

3. Assessment

The notified body shall:

3.1. examine and assess the technical documentation and verify that the type has been manufactured in conformity with that documentation; it shall also record the items designed in conformity with the applicable specifications of the standards referred to in Article 6 or CTS, as well as the items not designed on the basis of the relevant provisions of the abovementioned standards;

3.2. carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether the solutions adopted by the manufacturer meet the general safety and performance requirements of this Regulation if the standards referred to in Article 6 or CTS have not been applied; if the device is to be connected to other equipment in order to operate as intended, proof shall be provided that it conforms to the general safety and performance requirements when connected to any such equipment having the characteristics specified by the manufacturer;

3.3. carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether, if the manufacturer has chosen to apply the relevant standards, these have actually been applied;

3.4. agree with the applicant on the place where the necessary assessments and tests will be carried out;

3.5. in the case of devices classified as class D, ***or for companion diagnostics,*** request a reference laboratory, where designated in accordance with Article 78, to verify compliance of the device with the CTS or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent. The reference laboratory shall provide a scientific opinion within 30 days. The scientific opinion of the reference laboratory and any possible update shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision. The notified body shall not deliver the certificate if the scientific opinion is unfavourable; **[Am. 242]**

~~3.6. For companion diagnostic intended to be used to assess the patient eligibility to a treatment with a specific medicinal product, seek the opinion, on the basis of the draft summary of safety and performance and the draft instructions for use, of a one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC (hereinafter referred to as 'medicinal products competent authority') or the European Medicines Agency (hereinafter referred to as 'EMA') on the suitability of the device in relation to the medicinal product concerned. Where the medicinal product falls exclusively within the scope of the Annex of Regulation (EC) No 726/2004, the notified body shall consult the EMA. The medicinal products authority or the European Medicines Agency shall deliver its opinion, if any, within 60 days upon receipt of the valid documentation. This 60-day period may be extended only once for a further 60 days on scientifically valid grounds. The opinion of the medicinal products authority or of the EMA and any possible update shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the opinion, if any, expressed by the medicinal products competent authority concerned or the EMA when making its decision. It shall convey its final decision to the medicinal products competent authority concerned or to the EMA.~~ **[Am. 243]**

4. Certificate

If the type conforms to the provisions of this Regulation, the notified body shall issue an EU type-examination certificate. The certificate shall contain the name and address of the manufacturer, the conclusions of the assessment, the conditions of validity and the data needed for identification of the type approved. The relevant parts of the documentation shall be annexed to the certificate and a copy kept by the notified body.

5. Changes to the type

5.1. The applicant shall inform the notified body which issued the EU type-examination certificate of any planned change to the approved type.

5.2. Changes to the approved product shall receive further approval from the notified body which issued the EU type-examination certificate wherever the changes may affect conformity with the general safety and performance requirements or with the conditions prescribed for use of the product. The notified body shall examine the planned changes, notify the manufacturer of its decision and provide him with a supplement to the EU type-examination report. The approval of any change to the approved type shall take the form of a supplement to the initial EU type-examination certificate.

5.3. Where the changes could affect compliance with the CTS or with other solutions chosen by the manufacturer which were approved through the EU type-examination certificate, the notified body shall consult the reference laboratory that was involved in the initial consultation, in order to confirm that compliance with the CTS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent are maintained.

The reference laboratory shall provide a scientific opinion within 30 days.

~~5.4. Where the changes affect a companion diagnostic approved through the EU type-examination certificate with regard to its suitability in relation to a medicinal product, the notified body shall consult the medicinal products competent authority that was involved in the initial consultation or the EMA. The medicinal products competent authority or the EMA shall give its opinion, if any, within 30 days after receipt of the valid documentation regarding the changes. The approval of any change to the approved type shall take the form of a supplement to the initial EU type-examination certificate.~~ **[Am. 244]**

6. Administrative provisions

The manufacturer or his authorised representative shall, for a period ending at least five years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

- the documentation referred to in the second indent of Section 2,
- the changes referred to in Section 5,
- copies of EU type-examination certificates and their additions.

Section 8 of Annex VIII shall apply.

ANNEX X

CONFORMITY ASSESSMENT BASED ON PRODUCTION QUALITY ASSURANCE

1. The manufacturer shall ensure application of the quality management system approved for the manufacture of the devices concerned and carry out the final inspection, as specified in Section 3, and is subject to the surveillance referred to in Section 4.

2. The manufacturer who fulfils the obligations imposed by Section 1 shall draw up and keep an EU declaration of conformity in accordance with Article 15 and Annex III for the device model covered by the conformity assessment procedure. By issuing an EU declaration of conformity, the manufacturer ensures and declares that the devices concerned conform to the type described in the EU type-examination certificate and meet the provisions of this Regulation which apply to them.

3. Quality management system

3.1. The manufacturer shall lodge an application for assessment of his quality management system with a notified body.

The application shall include:

– all elements listed in Section 3.1 of Annex VIII,

– the technical documentation as referred to in Annex II for the types approved; where the technical documentation is voluminous and/or held in different locations, the manufacturer shall submit a summary technical documentation (STED) and grant access to the full technical documentation upon request;

– a copy of the EU-type examination certificates referred to in Section 4 of Annex IX; if the EU-type examination certificates have been issued by the same notified body with which the application is lodged, a reference to the technical documentation and the certificates issued is sufficient.

3.2. Application of the quality management system shall ensure that the devices conform to the type described in the EU type-examination certificate and to the provisions of this Regulation which apply to them at every stage. All the elements, requirements and provisions adopted by the manufacturer for his quality management system shall be documented in a systematic and orderly manner in the form of written policies and procedures such as quality programmes, quality plans, quality manuals and quality records.

It shall, in particular, include an adequate description of all elements listed in points (a), (b), (d) and (e) of Section 3.2 of Annex VIII.

3.3. The provisions of points (a) and (b) of Section 3.3 of Annex VIII, apply.

If the quality system ensures that the devices conform to the type described in the in the EU type-examination certificate and conforms to the relevant provisions of this Regulation, the notified body shall issue an EU quality assurance certificate. The decision shall be notified to the manufacturer. It shall contain the conclusions of the inspection and a reasoned assessment.

3.4. The provisions of the Section 3.4 of Annex VIII apply.

4. Surveillance

The provisions of Section 4.1, the first, second and fourth indents of Section 4.2, Section 4.3, Section 4.4, Section 4.6 and Section 4.7 of Annex VIII apply.

5. Verification of manufactured devices classified as class D

5.1. In the case of devices classified as class D, the manufacturer shall carry out tests on the manufactured devices or each batch of devices. After the conclusion of the controls and tests he shall forward to the notified body without delay the relevant reports on these tests. Furthermore, the manufacturer shall make the samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and modalities which shall include that the notified body or the manufacturer, ~~in regular intervals,~~ shall send samples of the manufactured devices or batches of devices to a reference laboratory, where designated in accordance with Article 78, to carry out appropriate ***laboratory*** tests. The reference laboratory shall inform the notified body about its findings **[Am. 245]**

5.2. The manufacturer may place the devices on the market, unless the notified body communicates to the manufacturer within the agreed time-frame, but not later than 30 days after reception of the samples, any other decision, including in particular any condition of validity of delivered certificates.

6. Administrative provisions

The manufacturer or his authorised representative shall, for a period ending at least five years after the last device has been placed on the market, keep at the disposal of the competent authorities:

- the declaration of conformity,
- the documentation referred to in the fourth indent of Section 3.1 of Annex VIII,
- the documentation referred to in the seventh indent of Section 3.1 of Annex VIII, including the EU type-examination certificate referred to in Annex IX,
- the changes referred to in Section 3.4 of Annex VIII and
- the decisions and reports from the notified body as referred to in Sections 3.3, 4.3 and 4.4 of Annex VIII.

Section 8 of Annex VIII shall apply.

ANNEX XI

MINIMUM CONTENT OF CERTIFICATES ISSUED BY A NOTIFIED BODY

1. Name, address and identification number of the notified body;
2. name and address of the manufacturer and, if applicable, of the authorised representative;
3. unique number identifying the certificate;
4. date of issue;
5. date of expiry;
6. data needed for the identification of the device(s) or categories of devices covered by the certificate, including the intended purpose of the device(s) and the GMDN code(s) or internationally recognised nomenclature code(s);
7. if applicable, the manufacturing facilities covered by the certificate;
8. reference to this Regulation and the relevant Annex according to which the conformity assessment has been carried out;

9. examinations and tests performed, e.g. reference to relevant standards / test reports / audit report(s);
10. if applicable, reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device(s) covered;
11. if applicable, information about the surveillance by the notified body;
12. conclusions of the notified body's assessment, examination or inspection;
13. conditions for or limitations to the validity of the certificate;
14. legally binding signature of the notified body according to the applicable national law.

ANNEX XII

CLINICAL EVIDENCE AND POST-MARKET FOLLOW-UP

Part A: Clinical evidence

The demonstration of conformity with the general safety and performance requirements set out in Annex I, under the normal conditions of use of the device, shall be based on clinical evidence.

The clinical evidence includes all the information supporting the scientific validity of the analyte, the analytical performance and, where applicable, the clinical performance of the device for its intended purpose as stated by the manufacturer.

1. SCIENTIFIC VALIDITY DETERMINATION AND PERFORMANCE EVALUATION

1.1. Scientific validity determination

1.1.1. The scientific validity refers to the association of the analyte to a clinical condition or a physiological state.

1.1.2. The determination of the scientific validity may not be necessary where the association of the analyte to a clinical condition or a physiological state is well known, based on available information, such as peer reviewed literature, historical data and experience.

1.1.3. For a new analyte and/or a new intended purpose, the scientific validity shall be demonstrated based on one or a combination of the following sources:

- information on devices measuring the same analyte with the same intended purpose that have marketing history;
- literature;
- expert opinions;
- results from proof of concept studies;
- results from clinical performance studies.

1.1.4. The information supporting the scientific validity of the analyte shall be summarised as part of the clinical evidence report.

1.2. Performance evaluation

The performance evaluation of a device is the process by which generated data are assessed and analysed to demonstrate the analytical performance, and where applicable the clinical performance of that device for its intended purpose as stated by the manufacturer.

Interventional performance studies and other clinical performance studies involving risks for the subjects of the studies shall only be performed once the analytical performance of the device has been established and determined to be acceptable.

1.2.1. Analytical performance

1.2.1.1 The analytical performance characteristics are described in point (a) of Section 6(1) of Annex I.

1.2.1.2 As a general rule, the analytical performance shall always be demonstrated on the basis of analytical performance studies.

1.2.1.3 For novel devices, it may not be possible to demonstrate trueness since suitable higher order reference materials or a suitable comparative method may not be available. If there are no comparative methods, different approaches may be used (e.g. comparison to some other well-documented method, comparison to the composite reference method). In the absence of such approaches, a clinical performance study comparing test performance to the current clinical standard practice would be needed.

1.2.1.4 The analytical performance ~~data~~ ***full dataset*** shall ***accompany the clinical evidence report and may*** be summarised as part of ~~the clinical evidence report~~ ***it***. **[Am. 246]**

1.2.2. Clinical performance

1.2.2.1 The clinical performance characteristics are described in point (b) of Section 6(1) of Annex I.

1.2.2.2 Clinical performance data may not be required for established and standardised devices and for devices classified as class A according to the rules set out in Annex VII.

1.2.2.3 Clinical performance of a device shall be demonstrated based on one or a combination of the following sources

- clinical performance studies;
- literature;
- experience gained by routine diagnostic testing.

1.2.2.4 Clinical performance studies shall be performed unless it is duly justified to rely on other sources of clinical performance data.

1.2.2.5 The clinical performance ~~data~~ ***full dataset*** shall ***accompany the clinical evidence report and may*** be summarised as part of ~~the clinical evidence report~~ ***it***. **[Am. 247]**

1.2.2.6 When the clinical performance evaluation includes a clinical performance study, the level of detail of the clinical performance study report referred to in Section 2.3.3 of this Annex will vary based on the risk class of the device determined according to the rules set out in Annex VII:

- For devices classified as class B according to the rules set out in Annex VII, the clinical performance study report may be limited to a summary of the study protocol, results and conclusion;
- For devices classified as class C according to the rules set out in Annex VII, the clinical performance study report shall include the method of data analysis, the study conclusion and the relevant details of the study protocol ***and the full dataset***; **[Am. 248]**
- For devices classified as class D according to the rules set out in Annex VII, the clinical performance study report shall include the method of data analysis, the study conclusion, the relevant details of the study protocol and the ~~individual data points~~ ***full dataset***. **[Am. 249]**

2. CLINICAL PERFORMANCE STUDIES

2.1. Purpose of clinical performance studies

The purpose of clinical performance studies is to establish or confirm aspects of device performance which cannot be determined by analytical performance studies, literature and/or previous experience gained by routine diagnostic testing. This information is used to demonstrate compliance with the relevant general safety and performance requirements with respect to clinical performance. When clinical performance studies are conducted, the data obtained shall be used in the performance evaluation process and be part of the clinical evidence for the device.

2.2. Ethical considerations for clinical performance studies

Every step in the clinical performance study, from first consideration of the need and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles, as for example those laid down in the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964 and last amended by the 59th World Medical Association General Assembly in Seoul, Korea, in 2008. ***Conformity with the above principles shall be granted after an examination by the ethics committee concerned.*** **[Am. 250]**

2.3. Methods for clinical performance studies

2.3.1. Clinical performance study design type

Clinical performance studies shall be designed in such a way as to maximize the relevance of the data while minimising potential biases. The design of the study shall provide the data necessary to address the clinical performance of the device.

2.3.2. Clinical performance study protocol

Clinical performance studies shall be performed on the basis of an appropriate 'clinical performance study protocol'.

The clinical performance study protocol shall set out how the study is intended to be conducted. It shall contain information about the study design such as the purpose, objectives, study population, description of test method(s) and interpretation of results, site training and monitoring, specimen type, specimen collection, preparation, handling and storage, inclusion and exclusion criteria, limitations, warning and precautions, data collection/management, data analysis, required materials, number of study sites and if applicable, clinical endpoints/outcomes, and requirements for patient follow-up.

In addition, the clinical performance study protocol shall identify the key factors which may impact the completeness and significance of results, such as intended participant follow-up procedures, decision algorithms, discrepancy resolution process, masking/blinding, approaches to statistical analyses, and methods for recording endpoints/outcomes and, where appropriate, communication of test results.

2.3.3. Clinical performance study report

A 'clinical performance study report', signed by a medical practitioner or any other authorised person responsible, shall contain documented information on the clinical performance study protocol, results and conclusions of the clinical performance study, including negative findings. The results and conclusions shall be transparent, free of bias and clinically relevant. The report shall contain sufficient information to enable it to be understood by an independent party without reference to other documents. The report shall also include as appropriate any protocol amendments or deviations, and data exclusions with the appropriate rationale. ***The report shall be accompanied by the clinical evidence report as described in point 3.1 and be accessible through the electronic system referred to in Article 51.*** **[Am. 251]**

3. CLINICAL EVIDENCE REPORT

3.1 The clinical evidence report shall contain the scientific validity data, the analytical performance data and, where applicable, the clinical performance data. If the analytical performance data is determined to be sufficient to declare conformity with the general safety and performance requirements set out to in Annex I without the need for clinical performance data, a rationale should be documented and included in the clinical evidence report.

3.2 The clinical evidence report shall in particular outline:

- the justification for the approach taken to gather the clinical evidence;
- the technology on which the device is based, the intended purpose of the device and any claims made about the device's clinical performance or safety;
- the nature and extent of the scientific validity and the performance data that has been evaluated;
- how the referenced information demonstrate the clinical performance and safety of the device in question;
- the literature search methodology, if a literature review is the approach taken to gathering clinical evidence.

3.3 The clinical evidence ***data*** and its documentation shall be updated throughout the life cycle of the device concerned with data obtained from the implementation of the manufacturer's post-market surveillance plan referred to in Article 8(5) which shall include a plan for the device post-market follow-up in accordance with Part B of this Annex. ***The clinical evidence data and its subsequent updates through post-market follow-up shall be accessible through the electronic systems referred to in Articles 51 and 60.*** **[Am. 252]**

Part B: Post-market follow-up

1. Manufacturers shall put in place procedures to enable them to collect and evaluate information relating to the scientific validity, as well as the analytical and clinical performance of their devices on the basis of data obtained from post-market follow-up.

2. Where such information becomes available to the manufacturer, an appropriate risk assessment shall be conducted and the clinical evidence report shall be amended accordingly.

3. Where changes to devices are necessary, the conclusion of the post market follow-up shall be taken into account for the clinical evidence referred to in Part A of this Annex and for the risk assessment referred to in Section 2 of Annex I. If necessary, the clinical evidence or risk management shall be updated and/or corrective actions be implemented.

4. Any new intended purpose of a device shall be supported by an updated clinical evidence report.

ANNEX XIII

INTERVENTIONAL CLINICAL PERFORMANCE STUDIES AND OTHER CLINICAL PERFORMANCE STUDIES INVOLVING RISKS FOR THE SUBJECTS OF THE STUDIES

I. Documentation regarding the application for interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies

For devices for performance evaluation intended to be used in the context of interventional clinical performance studies or other clinical performance studies involving risks for the subjects of the studies the sponsor shall draw up and submit the application in accordance with Article 49 accompanied by the documentation as laid down below:

1. Application form

The application form shall be duly filled out containing the following information:

1.1. Name, address and contact details of the sponsor and, if applicable, name, address and contact details of his contact person established in the Union.

1.2. If different from the above, name, address and contact details of the manufacturer of the device intended for performance evaluation and, if applicable, of his authorised representative.

1.3. Title of the clinical performance study.

1.4. Single identification number in accordance with Article 49(1).

1.5. Status of the clinical performance study (e.g. first submission, resubmission, significant amendment).

1.6. If resubmission with regard to same device, previous date(s) and reference number(s) of earlier submission(s) or in the case of significant amendment, reference to the original submission.

1.7. If parallel submission for a clinical trial on a medicinal product in accordance with Regulation (EU) No [Ref. of future Regulation on clinical trials], reference to the official registration number of the clinical trial.

1.8. Identification of the Member States, EFTA countries, Turkey and third countries in which the clinical performance study shall be conducted as part of a multicentre/ multinational study at the time of application.

1.9. Brief description of the device for performance evaluation (e.g. name, GMDN code or internationally recognised nomenclature code, intended purpose, risk class and applicable classification rule according to Annex VII).

1.10 Summary of the clinical performance study protocol.

1.11. If applicable, information regarding a comparator.

2. Investigator's Brochure

The investigator's brochure (IB) shall contain the information on the device for performance evaluation that is relevant for the study and available at the time of application. It shall be clearly identified and contain in particular the following information:

2.1. Identification and description of the device, including information on the intended purpose, the risk classification and applicable classification rule according to Annex VII, design and manufacturing of the device and reference to previous and similar generations of the device.

2.2. Manufacturer's instructions for installation, and use, including storage and handling requirements, as well as the label and instructions for use to the extent that this information is available.

2.3. Pre-clinical testing and experimental data.

2.4. Existing clinical data, in particular the following:

– relevant scientific literature available relating to the safety, performance, design characteristics and intended purpose of the device and/or of equivalent or similar devices;

– other relevant clinical data available relating to the safety, performance, design characteristics and intended purpose of equivalent or similar devices of the same manufacturer, including length of time on the market and a review of performance and safety related issues and any corrective actions taken.

2.5. Summary of the risk/benefit analysis and the risk management, including information regarding known or foreseeable risks and warnings.

2.6. In the case of devices that include tissues, cells and substances of human, animal or microbial origins detailed information on the tissues, cells and substances, and on the compliance with the relevant general safety and performance requirements and the specific risk management in relation to the tissues, cells and substances.

2.7. Reference to harmonised or other internationally recognised standards complied with in full or in part.

2.8. A clause that any updates to the IB or any other relevant information that is newly available shall be brought to the attention of the investigators.

3. Clinical performance study protocol, as referred to in Section 2.3.2 of Annex XII.

4. Other information

4.1. A signed statement by the natural or legal person responsible for the manufacture of the device for performance evaluation that the device in question conforms to the general safety and performance requirements apart from the aspects covered by the clinical performance study and that, with regard to these aspects, every precaution has been taken to protect the health and safety of the subject. This statement may be supported by an attestation issued by a notified body.

4.2. Where applicable according to national law, a copy of the opinion(s) of the ethics committee(s) concerned as soon as available.

4.3. Proof of insurance cover or indemnification of subjects in case of injury, according to the national law

4.4. Documents and procedures to be used to obtain informed consent.

4.5 Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data, in particular:

– organisational and technical arrangements that will be implemented to avoid unauthorised access, disclosure, dissemination, alteration or loss of information and personal data processed;

– a description of measures that will be implemented to ensure confidentiality of records and personal data of subjects concerned in clinical performance studies;

– a description of measures that will be implemented in case of data security breach in order to mitigate the possible adverse effects.

Ia. Incapacitated subjects and minors

1. Incapacitated subjects

In the case of incapacitated subjects who have not given, or who have not refused to give, informed consent before the onset of their incapacity, interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies may be conducted only where, in addition to the general conditions, all of the following conditions are met:

– ***the informed consent of the legal representative has been obtained; consent shall represent the subject's presumed will and may be revoked at any time, without detriment to the subject;***

– ***the incapacitated subject has received adequate information in relation to his or her capacity for understanding regarding the study and its risks and benefits from the investigator or his/her representative, in accordance with the national law of the Member State concerned;***

– ***the explicit wish of an incapacitated subject, who is capable of forming an opinion and assessing this information, to refuse participation in, or to be withdrawn from, the clinical performance study at any time without giving a reason and with no liability or prejudice whatsoever being incurred by the subject or their legal representative as a result, shall be followed by the investigator;***

– ***no incentives or financial inducements are given except compensation for participation in the clinical performance study;***

– ***such research is essential to validate data obtained in a clinical performance study on persons able to give informed consent or by other research methods;***

– ***such research relates directly to a medical condition from which the person concerned suffers;***

– ***the clinical performance study has been designed to minimise pain, discomfort, fear, and any other foreseeable risk in relation to the disease and the developmental stage and both the risk threshold and the degree of distress are specially defined and constantly observed;***

– ***the research is necessary to promote the health of the population concerned by the clinical performance study and cannot instead be performed on capacitated subjects;***

– ***there are grounds for expecting that participation in the clinical performance study will produce a benefit for the incapacitated subject outweighing the risks or will produce only a minimal risk;***

– *an ethics committee, with expertise regarding the relevant disease and the patient population concerned, or that has taken advice on clinical, ethical and psychosocial questions in the field of the relevant disease and patient population concerned, has endorsed the protocol;*

The test subject shall as far as possible take part in the consent procedure. **[Am. 253]**

2. Minors

An interventional clinical performance study and other clinical performance studies involving risks for the minor may be conducted only where, in addition to the general conditions, all of the following conditions are met:

– *the written informed consent of the legal representative or representatives has been obtained, whereby consent shall represent the minor's presumed will;*

- *the informed and express consent of the minor has been obtained, where the minor is able to give consent according to national law;*

– *the minor has received all relevant information in a way adapted to his or her age and maturity, from a medical doctor (either the investigator or member of the study team) trained or experienced in working with children, regarding the study, the risks and the benefits;*

– *without prejudice to the second indent, the explicit wish of a minor who is capable of forming an opinion and assessing this information to refuse participation in, or to be withdrawn from, the clinical performance study at any time, is duly taken into consideration by the investigator;*

– *no incentives or financial inducements are given except payment for participation in the clinical performance study;*

– *such research either relates directly to a medical condition from which the minor concerned suffers or is of such a nature that it can only be carried out on minors;*

– *the clinical performance study has been designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and developmental stage, and both the risk threshold and the degree of distress are specially defined and constantly observed;*

– *there are grounds to expect that some direct benefit for the category of patients concerned by the study may be obtained from the clinical performance study;*

– *the corresponding scientific guidelines of the Agency have been followed;*

- ***the interests of the patient shall always prevail over those of science and society;***
- ***the clinical performance study does not replicate other studies based on the same hypothesis and age-appropriate technology is used;***
- ***an ethics committee, with paediatric expertise or after taking advice in clinical, ethical and psychosocial problems in the field of paediatrics, has endorsed the protocol.***

The minor shall take part in the consent procedure in a manner adapted to his or her age and maturity. Minors who are able to give consent according to national law shall also give their informed and express consent to participate in the study.

If during a clinical performance study the minor reaches the age of majority as defined in the national law of the Member State concerned, his/her express informed consent shall be obtained before the study may continue. **[Am. 254]**

II. Other sponsor's obligations

1. The sponsor shall undertake to keep available for the competent national authorities any documentation necessary to provide evidence for the documentation referred to in Chapter I of this Annex. If the sponsor is not the natural or legal person responsible for the manufacture of the device intended for performance evaluation, this obligation may be fulfilled by that person on behalf of the sponsor.

2. The reportable events shall be provided by the investigator(s) in timely conditions.

3. The documentation mentioned in this Annex shall be kept for a period of time of at least five years after the clinical performance study with the device in question has ended, or, when the device is subsequently placed on the market, at least five years after the last device has been placed on the market.

Each Member State shall make provision that this documentation is kept at the disposal of the competent authorities for the period indicated in the preceding paragraph in case the sponsor, or his contact person, established within its territory goes bankrupt or ceases its activity prior to the end of this period.

ANNEX XIV

CORRELATION TABLE

Directive 98/79/EC	**This Regulation**
Article 1(1)	Article 1(1)
Article 1(2)	Article 2
Article 1(3)	Number (36) of Article 2
Article 1(4)	-
Article 1(5)	Article 4(4) and (5)
Article 1(6)	Article 1(6)
Article 1(7)	Article 1(4)
Article 2	Article 4(1)
Article 3	Article 4(2)
Article 4(1)	Article 20
Article 4(2)	Article 17(1)
Article 4(3)	Article 17(3)
Article 4(4)	Article 8(7)
Article 4(5)	Article 16(6)
Article 5(1)	Article 6(1)
Article 5(2)	-
Article 5(3)	Article 7
Article 6	-
Article 7	Article 84

Article 8	Articles 67 to 70
Article 9(1) 1st subparagraph	Article 40(5) 1st subparagraph
Article 9(1) 2nd subparagraph	Article 40(3) 2nd subparagraph and (4) 2nd subparagraph
Article 9(2)	Article 40(2)
Article 9(3)	Article 40(3)
Article 9(4)	Article 40(7)
Article 9(5)	-
Article 9(6)	Article 9(3)
Article 9(7)	Article 8(4)
Article 9(8)	Article 41(1)
Article 9(9)	Article 41(3)
Article 9(10)	Article 43(2)
Article 9(11)	Article 40(8)
Article 9(12)	Article 45(1)
Article 9(13)	Article 5(2)
Article 10	Article 23
Article 11(1)	Numbers (43) and (44) of Article 2, Article 59(1) and Article 61(1)
Article 11(2)	Article 59(3) and Article 61(1) 2nd subparagraph
Article 11(3)	Article 61(2) and (3)
Article 11(4)	-

Article 11(5)	Article 61(3) and Article 64
Article 12	Article 25
Article 13	Article 72
Article 14(1)(a)	Article 39(4)
Article 14(1)(b)	-
Article 14(2)	-
Article 14(3)	-
Article 15(1)	Article 31 and Article 32
Article 15(2)	Article 27
Article 15(3)	Article 33(1) and Article 34(2)
Article 15(4)	-
Article 15(5)	Article 43(4)
Article 15(6)	Article 43 (3)
Article 15(7)	Articles 29(2) and Article 33(1)
Article 16	Article 16
Article 17	Article 71
Article 18	Article 73
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