

SCHEDULE 1

Regulation 2(1)

(Annex I of the Directive)

Commencement Information

II Sch. 1 in force at 3.8.2017, see [reg. 1](#)

A. Essential requirements for the design and construction of products referred to in Article 2(1)

1. WATERCRAFT DESIGN CATEGORIES

Design category	Wind force(Beaufort scale)	Significant wave height(H 1/3, metres)
A	exceeding 8	exceeding 4
B	up to, and including, 8	up to, and including, 4
C	up to, and including, 6	up to, and including, 2
D	up to, and including, 4	up to, and including, 0,3

Explanatory notes:

- A. A recreational craft given design category A is considered to be designed for winds that may exceed wind force 8 (Beaufort scale) and significant wave height of 4 m and above but excluding abnormal conditions, such as storm, violent storm, hurricane, tornado and extreme sea conditions or rogue waves.
- B. A recreational craft given design category B is considered to be designed for a wind force up to, and including, 8 and significant wave height up to, and including, 4 m.
- C. A watercraft given design category C is considered to be designed for a wind force up to, and including, 6 and significant wave height up to, and including, 2 m.
- D. A watercraft given design category D is considered to be designed for a wind force up to, and including, 4 and significant wave height up to, and including, 0,3 m, with occasional waves of 0,5 m maximum height.

Watercraft in each design category must be designed and constructed to withstand the parameters in respect of stability, buoyancy, and other relevant essential requirements listed in this [F1Annex][F1Schedule], and to have good handling characteristics.

Textual Amendments

F1 Word in [Sch. 1 Pt. A](#) substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 28 para. 43\(2\)\(a\)](#) (with [Sch. 28 para. 41](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

2. GENERAL REQUIREMENTS

2.1. Watercraft identification

Each watercraft shall be marked with an identification number including the following information:

- ((1)) country code of the manufacturer,
- ((2)) unique code of the manufacturer assigned by [F2the national authority of the [F3relevant state]][F2or on behalf of the Secretary of State],
- ((3)) unique serial number,

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- ((4)) month and year of production,
 ((5)) model year.

Textual Amendments

- F2** Words in Sch. 1 Pt. A para. 2.1 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 28 para. 43(2)(b)(i)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F3** Words in Sch. 1 Pt. A para. 2.1 substituted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), **Sch. 15 para. 7(a)(i)**

Detailed requirements for the identification number referred to in the first paragraph are set out in the relevant [^{F4}harmonised][^{F4}designated] standard.

Textual Amendments

- F4** Word in Sch. 1 Pt. A para. 2.1 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 28 para. 43(2)(b)(ii)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

2.2. Watercraft builder's plate

Each watercraft shall carry a permanently affixed plate mounted separately from the watercraft identification number, containing at least the following information:

- ((a)) manufacturer's name, registered trade name or registered trade mark, as well as contact address;
- ((b)) [^{F5}CE marking, as provided for in Article 18;]
 [^{F5}UK marking, as provided for in regulation 54;]
- ((c)) watercraft design category in accordance with Section 1;
- ((d)) manufacturer's maximum recommended load derived from point 3.6 excluding the weight of the contents of the fixed tanks when full;
- ((e)) number of persons recommended by the manufacturer for which the watercraft was designed.

Textual Amendments

- F5** Words in Sch. 1 Pt. A para. 2.2 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 28 para. 43(2)(c)(i)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

In the case of post-construction assessment, the contact details and the requirements referred to in point (a) shall include those of the [^{F6}notified][^{F6}approved] body which has carried out the conformity assessment.

Textual Amendments

- F6** Word in Sch. 1 Pt. A para. 2.2 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 28 para. 43(2)(c)(ii)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

2.3. **Protection from falling overboard and means of reboarding**

Watercraft shall be designed to minimise the risks of falling overboard and to facilitate reboarding. Means of reboarding shall be accessible to or deployable by a person in the water unaided.

2.4. **Visibility from the main steering position**

For recreational craft, the main steering position shall give the operator, under normal conditions of use (speed and load), good all-round visibility.

2.5. **Owner's manual**

Each product shall be provided with an owner's manual [F7; in accordance with Article 7(7) and Article 9(4)] [F7; including the instructions and safety information referred to in regulations 15 and 22]. That manual shall provide all the information necessary for safe use of the product drawing particular attention to set up, maintenance, regular operation, prevention of risks and risk management.

Textual Amendments

F7 Words in Sch. 1 Pt. A para. 2.5 substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 28 para. 43(2)(d)** (with Sch. 28 para. 41) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

3. INTEGRITY AND STRUCTURAL REQUIREMENTS

3.1. **Structure**

The choice and combination of materials and its construction shall ensure that the watercraft is strong enough in all respects. Special attention shall be paid to the design category in accordance with Section 1, and the manufacturer's maximum recommended load in accordance with point 3.6.

3.2. **Stability and freeboard**

The watercraft shall have sufficient stability and freeboard considering its design category in accordance with Section 1 and the manufacturer's maximum recommended load in accordance with point 3.6.

3.3. **Buoyancy and flotation**

The watercraft shall be constructed as to ensure that it has buoyancy characteristics appropriate to its design category in accordance with Section 1 and the manufacturer's maximum recommended load in accordance with point 3.6. All habitable multihull recreational craft susceptible of inversion shall have sufficient buoyancy to remain afloat in the inverted position.

Watercraft of less than 6 metres in length that are susceptible to swamping when used in their design category shall be provided with appropriate means of flotation in the swamped condition.

3.4. **Openings in hull, deck and superstructure**

Openings in hull, deck(s) and superstructure shall not impair the structural integrity of the watercraft or its weather tight integrity when closed.

Windows, port lights, doors and hatch covers shall withstand the water pressure likely to be encountered in their specific position, as well as point loads applied by the weight of persons moving on deck.

Through hull fittings designed to allow water passage into the hull or out of the hull, below the waterline corresponding to the manufacturer's maximum recommended load in accordance with point 3.6, shall be fitted with a means of shutoff which shall be readily accessible.

3.5. **Flooding**

All watercraft shall be designed so as to minimise the risk of sinking.

Where appropriate, particular attention shall be paid to:

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- ((a)) cockpits and wells, which should be self-draining or have other means of keeping water out of the watercraft interior;
- ((b)) ventilation fittings;
- ((c)) removal of water by pumps or other means.

3.6. **Manufacturer's maximum recommended load**

The manufacturer's maximum recommended load (fuel, water, provisions, miscellaneous equipment and people (in kilograms)) for which the watercraft was designed, shall be determined in accordance with the design category (Section 1), stability and freeboard (point 3.2) and buoyancy and flotation (point 3.3).

3.7. **Life raft stowage**

All recreational craft of design categories A and B, and recreational craft of design categories C and D longer than 6 metres shall be provided with one or more stowage points for a life raft (life rafts) large enough to hold the number of persons the recreational craft was designed to carry as recommended by the manufacturer. Life raft stowage point(s) shall be readily accessible at all times.

3.8. **Escape**

All habitable multihull recreational craft susceptible of inversion shall be provided with viable means of escape in the event of inversion. Where there is a means of escape provided for use in the inverted position, it shall not compromise the structure (point 3.1), the stability (point 3.2) or buoyancy (point 3.3) whether the recreational craft is upright or inverted.

Every habitable recreational craft shall be provided with viable means of escape in the event of fire.

3.9. **Anchoring, mooring and towing**

All watercraft, taking into account their design category and their characteristics, shall be fitted with one or more strong points or other means capable of safely accepting anchoring, mooring and towing loads.

4. **HANDLING CHARACTERISTICS**

The manufacturer shall ensure that the handling characteristics of the watercraft are satisfactory with the most powerful propulsion engine for which the watercraft is designed and constructed. For all propulsion engines, the maximum rated engine power shall be declared in the owner's manual.

5. **INSTALLATION REQUIREMENTS**

5.1. **Engines and engine compartments**

5.1.1. *Inboard engine*

All inboard mounted engines shall be placed within an enclosure separated from living quarters and installed so as to minimise the risk of fires or spread of fires as well as hazards from toxic fumes, heat, noise or vibrations in the living quarters.

Engine parts and accessories that require frequent inspection and/or servicing shall be readily accessible.

The insulating materials inside the engine compartment shall not sustain combustion.

5.1.2. *Ventilation*

The engine compartment shall be ventilated. The ingress of water into the engine compartment through openings must be minimised.

5.1.3. *Exposed parts*

Unless the engine is protected by a cover or its own enclosure, exposed moving or hot parts of the engine that could cause personal injury shall be effectively shielded.

5.1.4. *Outboard propulsion engine starting*

Every outboard propulsion engine fitted on any watercraft shall have a device to prevent the engine being started in gear, except:

- (a) when the engine produces less than 500 Newton's (N) of static thrust;
- (b) when the engine has a throttle limiting device to limit thrust to 500 N at the time of starting the engine.

5.1.5. *Personal watercraft running without driver*

Personal watercraft shall be designed either with an automatic propulsion engine cut-off or with an automatic device to provide reduced speed, circular, forward movement when the driver dismounts deliberately or falls overboard.

5.1.6. Tiller-controlled outboard propulsion engines shall be equipped with an emergency stopping device which can be linked to the helmsman.

5.2. **Fuel system**

5.2.1. *General*

The filling, storage, venting and fuel-supply arrangements and installations shall be designed and installed so as to minimise the risk of fire and explosion.

5.2.2. *Fuel tanks*

Fuel tanks, lines and hoses shall be secured and separated or protected from any source of significant heat. The material the tanks are made of and their method of construction shall be in accordance with their capacity and the type of fuel.

Petrol fuel tank spaces shall be ventilated.

Petrol fuel tanks shall not form part of the hull and shall be:

- (a) protected against fire from any engine and from all other sources of ignition;
- (b) separated from living quarters.

Diesel fuel tanks may be integral with the hull.

5.3. **Electrical system**

Electrical systems shall be designed and installed so as to ensure proper operation of the watercraft under normal conditions of use and shall be such as to minimise risk of fire and electric shock.

All electrical circuits, except engine starting circuits supplied from batteries, shall remain safe when exposed to overload.

Electric propulsion circuits shall not interact with other circuits in such a way that either would fail to operate as intended.

Ventilation shall be provided to prevent the accumulation of explosive gases which might be emitted from batteries. Batteries shall be firmly secured and protected from ingress of water.

5.4. **Steering system**

5.4.1. *General*

Steering and propulsion control systems shall be designed, constructed and installed in order to allow the transmission of steering loads under foreseeable operating conditions.

5.4.2. *Emergency arrangements*

Every sailing recreational craft and single-propulsion engine non-sailing recreational craft with remote-controlled rudder steering systems shall be provided with emergency means of steering the recreational craft at reduced speed.

5.5. **Gas system**

Gas systems for domestic use shall be of the vapour-withdrawal type and shall be designed and installed so as to avoid leaks and the risk of explosion and be capable of being tested for leaks.

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Materials and components shall be suitable for the specific gas used to withstand the stresses and exposures found in the marine environment.

Each gas appliance intended by the manufacturer for the application for which it is used shall be so installed in accordance with the manufacturer's instructions. Each gas-consuming appliance must be supplied by a separate branch of the distribution system, and each appliance must be controlled by a separate closing device. Adequate ventilation must be provided to prevent hazards from leaks and products of combustion.

All watercraft with a permanently installed gas system shall be fitted with an enclosure to contain all gas cylinders. The enclosure shall be separated from the living quarters, accessible only from the outside and ventilated to the outside so that any escaping gas drains overboard.

In particular, any permanently installed gas system shall be tested after installation.

5.6. **Fire protection**

5.6.1. *General*

The type of equipment installed and the layout of the watercraft shall take account of the risk and spread of fire. Special attention shall be paid to the surroundings of open flame devices, hot areas or engines and auxiliary machines, oil and fuel overflows, uncovered oil and fuel pipes and routing of electrical wiring in particular away from heat sources and hot areas.

5.6.2. *Fire-fighting equipment*

Recreational craft shall be supplied with fire-fighting equipment appropriate to the fire hazard, or the position and capacity of fire-fighting equipment appropriate to the fire hazard shall be indicated. The craft shall not be put into service until the appropriate fire-fighting equipment is in place. Petrol engine compartments shall be protected by a fire extinguishing system that avoids the need to open the compartment in the event of fire. Where fitted, portable fire extinguishers shall be readily accessible and one shall be so positioned that it can easily be reached from the main steering position of the recreational craft.

5.7. **Navigation lights, shapes and sound signals**

Where navigation lights, shapes and sound signals are fitted, they shall comply with the 1972 COLREG (The International Regulations for Preventing Collisions at Sea) or CEVNI (European Code for Interior Navigations for inland waterways) Regulations as appropriate.

5.8. **Discharge prevention and installations facilitating the delivery ashore of waste**

Watercraft shall be constructed so as to prevent the accidental discharge of pollutants (oil, fuel, etc.) overboard.

Any toilet fitted in a recreational craft shall be connected solely to a holding tank system or water treatment system.

Recreational craft with installed holding tanks shall be fitted with a standard discharge connection to enable pipes of reception facilities to be connected with the recreational craft discharge pipeline.

In addition, any through-the-hull pipes for human waste shall be fitted with valves which are capable of being secured in the closed position.

B. **Essential requirements for exhaust emissions from propulsion engines**

Propulsion engines shall comply with the essential requirements for exhaust emissions set out in this Part.

1. **PROPULSION ENGINE IDENTIFICATION**

1.1. Each engine shall be clearly marked with the following information:

- ((a)) engine manufacturer's name, registered trade name or registered trade mark and contact address; and, if applicable, the name and contact address of the person adapting the engine;
- ((b)) engine type, engine family, if applicable;

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- ((c)) a unique engine serial number;
- ((d)) [^{F8}CE marking, as provided for in Article 18.]
[^{F8}UK marking, as provided for in regulation 54.]

Textual Amendments

F8 Words in Sch. 1 Pt. B para. 1.1 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 28 para. 43(3)(a) (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 1.2. The marks referred to in point 1.1 must be durable for the normal life of the engine and must be clearly legible and indelible. If labels or plates are used, they must be attached in such a manner that the fixing is durable for the normal life of the engine, and the labels/plates cannot be removed without destroying or defacing them.
- 1.3. The marks must be secured to an engine part necessary for normal engine operation and not normally requiring replacement during the engine life.
- 1.4. The marks must be located so as to be readily visible after the engine has been assembled with all the components necessary for engine operation.

2. EXHAUST EMISSION REQUIREMENTS

Propulsion engines shall be designed, constructed and assembled so that when correctly installed and in normal use, emissions shall not exceed the limit values obtained from point 2.1, Table 1 and point 2.2, Tables 2 and 3:

- 2.1. Values applying for the purposes of Article 55(2) and Table 2 of point 2.2:

Table 1

(g/kWh)	Carbon monoxide	Hydrocarbons	Nitrogen oxides	Particulates	PT
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$$CO = A + B / P_n^N$$

$$HC = A + B / P_n^N$$

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	A	B	n	A	B	n		
Two-stroke spark ignition	150,0	600,0	1,0	30,0	100,0	0,75	10,0	Not applicable
Four-stroke spark ignition	150,0	600,0	1,0	6,0	50,0	0,75	15,0	Not applicable
Compression ignition	150,0	0	0	1,5	2,0	0,5	9,8	1,0

Where A, B and n are constants in accordance with the table, P_N is the rated engine power in kW.

2.2. Values applying from 18 January 2016:

Table 2

Exhaust emission limits for compression ignition (CI) engines(2)

Swept Volume SV(L/cyl)	Rated Engine Power P_N(kW)	Particulates PT(g/kWh)	Hydrocarbons + Nitrogen Oxides HC + NO_x (g/kWh)
SV < 0,9	P_N < 37	The values referred to in table 1	
	37 ≤ P_N < 75	0,3	4,7
	75 ≤ P_N < 3700	0,15	5,8
0,9 ≤ SV < 1,2	P_N < 3700	0,14	5,8
1,2 ≤ SV < 2,5		0,12	5,8
2,5 ≤ SV < 3,5		0,12	5,8
3,5 ≤ SV < 7,0		0,11	5,8

a + Alternatively, compression-ignition engines with rated engine power at or above 37 kW and below 75 kW and with a swept volume below 0,9 L/cyl shall not exceed a PT emission limit of 0,20 g/kWh and a combined **HC + NO_x** emission limit of 5,8 g/kWh.

b ++ Any compression-ignition engine shall not exceed a Carbon monoxide (CO) emission limit of 5,0 g/kWh.

Table 3

Exhaust emission limits for spark ignition (SI) engines

Type of engine	Rated Engine Power P_N(kW)	Carbon monoxide CO(g/kWh)	Hydrocarbons + Nitrogen Oxides HC + NO_x (g/kWh)
Stern-drive and inboard engines	P_N ≤ 373	75	5

(2) 2015 c.26

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	$373 < P_N \leq 485$	350	16
	$P_N > 485$	350	22
Outboard engines and PWC engines	$P_N \leq 4,3$	$500 - (5,0 \times P_N)$	30
	$4,3 < P_N \leq 40$	$500 - (5,0 \times P_N)$	$15,7 + \left(\frac{50}{P_N^{0,9}}\right)$
	$P_N > 40$	300	$15,7 + \left(\frac{50}{P_N^{0,9}}\right)$

2.3. Test cycles:

Test cycles and weighting factors to be applied:

The following requirements of ISO standard 8178-4:2007 shall be used, taking into account the values set out in the table below.

For variable speed CI engines test cycle E1 or E5 shall be applied or alternatively, above 130 kW, test cycle E3 may be applied. For variable speed SI engines test cycle E4 shall be applied.

Cycle E1, Mode number	1	2	3	4	5	
Speed	Rated speed		Intermediate speed		Low-idle speed	
Torque, %	100	75	75	50	0	
Weighting factor	0,08	0,11	0,19	0,32	0,3	
Speed	Rated speed		Intermediate speed		Low-idle speed	
Cycle E3, Mode number	1		2	3	4	
Speed, %	100		91	80	63	
Power, %	100		75	50	25	
Weighting factor	0,2		0,5	0,15	0,15	
Cycle E4, Mode number	1		2	3	4	5
Speed, %	100		80	60	40	Idle
Torque, %	100		71,6	46,5	25,3	0
Weighting factor	0,06		0,14	0,15	0,25	0,4
Cycle E5, Mode number	1		2	3	4	5
Speed, %	100		91	80	63	Idle
Power, %	100		75	50	25	0

Weighting factor	0,08	0,13	0,17	0,32	0,3
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[^{F9}Notified][^{F9}Approved] bodies may accept tests carried out on the basis of other tests cycles as specified in a [^{F10}harmonised][^{F10}designated] standard and as applicable for the engine duty cycle.

Textual Amendments

- F9** Word in Sch. 1 Pt. B para. 2.3 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 28 para. 43(3)(b)(i) (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F10** Word in Sch. 1 Pt. B para. 2.3 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 28 para. 43(3)(b)(ii) (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

2.4. Application of the propulsion engine family and choice of parent propulsion engine

The engine manufacturer shall be responsible for defining those engines from his range which are to be included in an engine family.

A parent engine shall be selected from an engine family in such a way that its emissions characteristics are representative for all engines in that engine family. The engine incorporating those features that are expected to result in the highest specific emissions (expressed in g/kWh), when measured on the applicable test cycle, should normally be selected as the parent engine of the family.

2.5. Test fuels

The test fuel used for exhaust emission testing shall meet the following characteristics:

Petrol Fuels				
Property	RF-02-99Unleaded		RF-02-03Unleaded	
	min	max	min	max
Research Octane Number (RON)	95	—	95	—
Motor Octane Number (MON)	85	—	85	—
Density at 15 °C (kg/m ³)	748	762	740	754
Initial boiling point (°C)	24	40	24	40
Mass fraction of sulphur (mg/kg)	—	100	—	10
Lead content (mg/l)	—	5	—	5
Reid vapour pressure (kPa)	56	60	—	—
Vapour pressure (DVPE) (kPa)	—	—	56	60
Diesel Fuels				
Property	RF-06-99		RF-06-03	

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	min	max	min	max
Cetane number	52	54	52	54
Density at 15 °C (kg/m ³)	833	837	833	837
Final boiling point (°C)	—	370	—	370
Flash point (°C)	55	—	55	—
Mass fraction of sulphur (mg/kg)	To be reported	300 (50)	—	10
Mass fraction of ash (%)	To be reported	0,01	—	0,01

[^{F11}Notified][^{F11}Approved] bodies may accept tests carried out on the basis of other tests fuel as specified in a [^{F12}harmonised][^{F12}designated] standard.

Textual Amendments

- F11** Word in Sch. 1 Pt. B para. 2.5 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 28 para. 43(3)(b)(i) (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F12** Word in Sch. 1 Pt. B para. 2.5 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 28 para. 43(3)(b)(ii) (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

3. DURABILITY

The manufacturer of the engine shall supply engine installation and maintenance instructions, which if applied should mean that the engine in normal use will continue to comply with the limits set out in points 2.1 and 2.2 throughout the normal life of the engine and under normal conditions of use.

This information shall be obtained by the engine manufacturer by use of prior endurance testing, based on normal operating cycles, and by calculation of component fatigue so that the necessary maintenance instructions may be prepared by the manufacturer and issued with all new engines when first placed on the market.

The normal life of the engine is as follows:

- ((a)) For CI engines: 480 hours of operation or 10 years, whichever occurs first;
- ((b)) For SI inboard or stern drive engines with or without integral exhaust:
- ((i)) for the engine category
 $P_N \leq 373 \text{ kW}$
: 480 hours of operation or 10 years, whichever occurs first,
- ((ii)) for engines in the category
 $373 < P_N \leq 485 \text{ kW}$
: 150 hours of operation or three years, whichever occurs first,
- ((iii)) for the engine category
 $P_N > 485 \text{ kW}$
: 50 hours of operation or one year, whichever occurs first;
- ((c)) personal watercraft engines: 350 hours of operation or five years, whichever occurs first;

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((d)) outboard engines: 350 hours of operation or 10 years, whichever occurs first

4. OWNER'S MANUAL

Each engine shall be provided with an owner's manual in [^{F13}a language or languages which can be easily understood by consumers and other end-users, as determined by the [^{F14}relevant state] in which the engine is to be marketed][^{F13}English].

Textual Amendments

- F13** Word in Sch. 1 Pt. B para. 4 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 28 para. 43(3)(c)(i) (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F14** Words in Sch. 1 Pt. B para. 4 substituted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), Sch. 15 para. 7(a)(ii)

The owner's manual shall:

- ((a)) provide instructions for the installation, use and maintenance needed to assure the proper functioning of the engine to meet the requirements of Section 3 (Durability);
- ((b)) specify the power of the engine when measured in accordance with the [^{F15}harmonised][^{F15}designated] standard.

Textual Amendments

- F15** Word in Sch. 1 Pt. B para. 4 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 28 para. 43(3)(c)(ii) (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

C. Essential requirements for noise emissions

Recreational craft with inboard or stern drive engines without integral exhaust, personal watercraft and outboard engines and stern drive engines with integral exhaust shall comply with the essential requirements for noise emissions set out in this Part.

1. NOISE EMISSION LEVELS

- 1.1. Recreational craft with inboard or stern drive engines without integral exhaust, personal watercraft and outboard engines and stern drive engines with integral exhaust shall be designed, constructed and assembled so that noise emissions shall not exceed the limit values in the following table:

Rated Engine Power(single engine)In kW	Maximum Sound Pressure Level = L _{pASmax} In dB
$P_N \leq 10$	67
$10 < P_N \leq 40$	72
$P_N > 40$	75

where P_N = rated engine power in kW of a single engine at rated speed and L_{pASmax} = maximum sound pressure level in dB.

For twin-engine and multiple-engine units of all engine types an allowance of 3 dB may be applied.

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- 1.2. As an alternative to sound measurement tests, recreational craft with inboard engine configuration or stern drive engine configuration, without integral exhaust, shall be deemed to comply with the noise requirements set out in point 1.1 if they have a Froude number of $\leq 1,1$ and a Power to Displacement ratio of ≤ 40 and where the engine and exhaust system are installed in accordance with the engine manufacturer's specifications.
- 1.3. 'Froude number' F_n shall be calculated by dividing the maximum recreational craft speed V (m/s) by the square root of the waterline length lwl (m) multiplied by a given gravitational acceleration constant, g , of $9,8 \text{ m/s}^2$.

$$F_n = \frac{V}{\sqrt{(g \cdot lwl)}}$$

'Power to Displacement ratio' shall be calculated by dividing the rated engine power P_N (in kW) by the recreational craft's displacement D (in tonnes)

$$\text{Power to Displacement ratio} = \frac{P_N}{D}$$

2. OWNER'S MANUAL

For recreational craft with inboard engine or stern drive engines without integral exhaust and personal watercraft, the owner's manual required under point 2.5 of Part A, shall include information necessary to maintain the recreational craft and exhaust system in a condition that, insofar as is practicable, will ensure compliance with the specified noise limit values when in normal use.

For outboard engines and stern drive engines with integral exhaust, the owner's manual required under Section 4 of Part B shall provide the instructions necessary to maintain the engine in a condition, that insofar as is practicable, will ensure compliance with the specified noise limit values when in normal use.

3. DURABILITY

The provisions on the durability in Section 3 of Part B shall apply mutatis mutandis to the compliance with the requirements on noise emissions set out in Section 1 of this part.

SCHEDULE 2

Regulation 2(1)

(Annex II of the Directive) COMPONENTS OF WATERCRAFT

Commencement Information

I2 Sch. 2 in force at 3.8.2017, see [reg. 1](#)

- (1) Ignition-protected equipment for inboard and stern drive petrol engines and petrol tank spaces;
- (2) Start-in-gear protection devices for outboard engines;
- (3) Steering wheels, steering mechanisms and cable assemblies;
- (4) Fuel tanks intended for fixed installations and fuel hoses;
- (5) Prefabricated hatches, and port lights.

SCHEDULE 3

Regulation 7

(Annex III of the Directive)
**DECLARATION BY THE MANUFACTURER OR THE IMPORTER
OF THE PARTLY COMPLETED WATERCRAFT (ARTICLE 6(2))**

Commencement Information

I3 Sch. 3 in force at 3.8.2017, see [reg. 1](#)

The declaration by the manufacturer or the importer [^{F16}established in the Union referred to in Article 6(2)] [^{F16}established in the United Kingdom referred to in regulation 7(1)(b)] shall contain the following:

Textual Amendments

F16 Words in Sch. 3 substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 28 para. 44\(a\)](#) (with [Sch. 28 para. 41](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

- ((a)) the name and address of the manufacturer;
- ((b)) the name and address of the representative of the manufacturer [^{F17}established in the Union] [^{F17}established in the United Kingdom] or, if appropriate, of the person responsible for the placing on the market;
- ((c)) a description of the partly completed watercraft;
- ((d)) a statement that the partly completed watercraft complies with the essential requirements that apply at this stage of construction; this shall include references to the relevant [^{F18}harmonised] [^{F18}designated] standards used, or references to the specifications in relation to which compliance is declared at this stage of construction; furthermore, it is intended to be completed by other legal or natural persons in full compliance with [^{F19}this Directive] [^{F19}these Regulations].

Textual Amendments

F17 Words in [Sch. 3](#) substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 28 para. 44\(b\)](#) (with [Sch. 28 para. 41](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

F18 Word in [Sch. 3](#) substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 28 para. 44\(c\)\(i\)](#) (with [Sch. 28 para. 41](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

F19 Words in [Sch. 3](#) substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 28 para. 44\(c\)\(ii\)](#) (with [Sch. 28 para. 41](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

SCHEDULE 4

Regulation 10

(Annex IV of the Directive)

[^{F20}EU] DECLARATION OF CONFORMITY No xxxxx**Textual Amendments**

F20 Word in Sch. 4 heading omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 28 para. 45(a) (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I4 Sch. 4 in force at 3.8.2017, see **reg. 1**

1. No xxxxx (Product: product, batch, type, or serial number):
2. Name and address of the manufacturer or his authorised representative [The authorised representative must also give the business name and address of the manufacturer] or the private importer.
3. This declaration of conformity is issued under the sole responsibility of the manufacturer or the private importer or the person referred to in [^{F21}Article 19(3) or (4) of Directive 2013/53/EU][^{F21}regulation 43(2) or (3) of the Recreational Craft Regulations 2017 (S.I. 2017/737, “the Regulations”)].
4. Object of the declaration (identification of product allowing traceability. It may include a photograph, where appropriate):
5. The object of the declaration described in point 4 is in conformity with the relevant [^{F22}Union harmonisation legislation][^{F22}statutory requirements]:
6. References to the relevant [^{F23}harmonised][^{F23}designated] standards used or references to the other technical specifications in relation to which conformity is declared:
7. Where applicable, the [^{F24}notified][^{F24}approved] body ... (name, number) performed ... (description of intervention) and issued the certificate:
8. Identification of the person empowered to sign on behalf of the manufacturer or his authorised representative
9. Additional information:

The [^{F25}EU] declaration of conformity shall include a statement of the propulsion engine manufacturer and that of the person adapting an engine in accordance with [^{F26}points (b) and (c) of Article 6(4)][^{F26}regulation 7(1)(c)(iii)] that:

(a) when installed in a watercraft, in accordance with the installation instructions accompanying the engine, the engine will meet:

- (i) the exhaust emission requirements of [^{F27}this Directive][^{F27}the Regulations];
- (ii) [^{F28}the limits of Directive 97/68/EC as regards engines type-approved in accordance with Directive 97/68/EC which are in compliance with stage III A, stage III B or stage IV emission limits for CI engines used in other applications than propulsion of inland waterway vessels, locomotives and railcars, as provided for in point 4.1.2 of Annex I to that Directive;] or
- (iii) the limits of Regulation (EC) No 595/2009 as regards engines type-approved in accordance with that Regulation.

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The engine must not be put into service until the watercraft into which it is to be installed has been declared in conformity, if so required, with the relevant provision of [^{F27}this Directive][^{F27}the Regulations].

If the engine has been placed on the market during the additional transitional period provided for in [^{F29}Article 55(2)][^{F29}regulation 89(2)], the [^{F25}EU] declaration of conformity shall contain an indication thereof.

Signed for and on behalf of:

(place and date of issue)

(name, function) (signature)

Textual Amendments

- F21** Words in Sch. 4 para. 3 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 28 para. 45(b)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F22** Words in Sch. 4 para. 5 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 28 para. 45(c)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F23** Word in Sch. 4 para. 6 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 28 para. 45(d)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F24** Word in Sch. 4 para. 7 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 28 para. 45(e)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F25** Word in Sch. 4 para. 9 omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 28 para. 45(f)(i)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F26** Words in Sch. 4 para. 9 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 28 para. 45(f)(ii)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F27** Words in Sch. 4 para. 9 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 28 para. 45(f)(iii)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F28** Words in Sch. 4 para. 9 omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 28 para. 45(f)(iv)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F29** Words in Sch. 4 para. 9 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 28 para. 45(f)(v)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

SCHEDULE 5

Regulation 48

(Annex V of the Directive)
**EQUIVALENT CONFORMITY BASED ON POST-
 CONSTRUCTION ASSESSMENT (MODULE PCA)**

Commencement Information

I5 Sch. 5 in force at 3.8.2017, see [reg. 1](#)

1. Conformity based on post-construction assessment is the procedure to assess the equivalent conformity of a product for which the manufacturer has not assumed the responsibility for the product's conformity with [F30this Directive][F30these Regulations], and whereby a natural or legal person referred to in [F31Article 19(2), (3) or (4)][F31regulation 43(1), (2) or (3)] who is placing the product on the market or putting it into service under his own responsibility is assuming the responsibility for the equivalent conformity of the product. This person shall fulfill the obligations laid down in points 2 and 4 and ensure and declare on his sole responsibility that the product concerned, which has been subject to the provisions of point 3, is in conformity with the applicable requirements of [F30this Directive][F30these Regulations].

2. The person who is placing the product on the market or putting it into service shall lodge an application for a post-construction assessment of the product with [F32a notified][F32an approved] body and must provide [F33the notified][F33the approved] body with the documents and technical file enabling [F33the notified][F33the approved] body to assess the conformity of the product with the requirements of [F30this Directive][F30these Regulations] and any available information on the use of the product after its first putting into service.

The person who is placing such a product on the market or putting it into service shall keep these documents and information at the disposal of the [F34relevant national authorities][F34enforcing authority] for 10 years after the product has been assessed on its equivalent conformity in accordance with the post-construction assessment procedure.

3. The [F35notified][F35approved] body shall examine the individual product and carry out calculations, tests and other assessments, to the extent necessary to ensure that the equivalent conformity of the product with the relevant requirements of [F30this Directive][F30these Regulations] is demonstrated.

The [F35notified][F35approved] body shall draw up and issue a certificate and a related report of conformity concerning the assessment carried out and shall keep a copy of the certificate and related report of conformity at the disposal of the [F36national authorities][F36enforcing authority] for 10 years after it has issued these documents.

The [F35notified][F35approved] body shall affix its identification number next to the [F37CE][F37UK] marking on the approved product or have it affixed under its responsibility.

In case the assessed product is a watercraft, the [F35notified][F35approved] body shall also have affixed, under his responsibility, the watercraft identification number as referred to in point 2.1 of Part A of [F38Annex I][F38Schedule 1], whereby the field for the country code of the manufacturer shall be used to indicate the country of establishment of the [F35notified][F35approved] body and the fields for the unique code of the manufacturer assigned by [F39the national authority of the [F40relevant state]][F39or on behalf of the Secretary of State] to indicate the post-construction assessment identification code assigned to the [F35notified][F35approved] body, followed by the serial number of the post-construction assessment certificate. The fields in the watercraft identification number for the month and

year of production and for the model year shall be used to indicate the month and year of the post-construction assessment.

4. [F41CE marking and EU declaration of conformity][F41UK marking and declaration of conformity]
 - 4.1. The person who is placing the product on the market or putting it into service shall affix the [F42CE][F42UK] marking and, under the responsibility of the [F43notified][F43approved] body referred to in Section 3, the latter's identification number to the product for which the [F43notified][F43approved] body has assessed and certified its equivalent conformity with the relevant requirements of [F30this Directive][F30these Regulations].
 - 4.2. The person who is placing the product on the market or putting it into service shall draw up [F44an EU][F44a] declaration of conformity and keep it at the disposal of the [F45national authorities][F45enforcing authority] for 10 years after the date the post-construction assessment certificate has been issued. The declaration of conformity shall identify the product for which it has been drawn up.

A copy of [F46the EU][F46the] declaration of conformity shall be made available to the [F47relevant authorities][F47enforcing authority] upon request.
 - 4.3. In the case the assessed product is a watercraft, the person who is placing the watercraft on the market or putting it into service shall affix to the watercraft the builder's plate described in point 2.2 of Part A of [F48Annex I][F48Schedule 1], which shall include the words 'post-construction assessment', and the watercraft identification number described in point 2.1 of Part A of [F48Annex I][F48Schedule 1], in accordance with the provisions set out in Section 3.
5. The [F49notified][F49approved] body shall inform the person who is placing the product on the market or putting it into service of his obligations under this post-construction assessment procedure.

Textual Amendments

- F30** Words in Sch. 5 substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 28 para. 46(2)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F31** Words in Sch. 5 para. 1 substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 28 para. 46(3)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F32** Words in Sch. 5 para. 2 substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 28 para. 46(4)(a)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F33** Words in Sch. 5 para. 2 substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 28 para. 46(4)(b)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F34** Words in Sch. 5 para. 2 substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 28 para. 46(4)(c)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F35** Word in Sch. 5 para. 3 substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 28 para. 46(5)(a)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F36** Words in Sch. 5 para. 3 substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 28 para. 46(5)(b)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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- F37** Word in Sch. 5 para. 3 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 28 para. 46(5)(c)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F38** Words in Sch. 5 para. 3 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 28 para. 46(5)(d)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F39** Words in Sch. 5 para. 3 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 28 para. 46(5)(e)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F40** Words in Sch. 5 para. 3 substituted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), **Sch. 15 para. 7(b)**
- F41** Words in Sch. 5 para. 4 heading substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 28 para. 46(6)(a)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F42** Words in Sch. 5 para. 4.1 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 28 para. 46(6)(b)(i)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F43** Word in Sch. 5 para. 4.1 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 28 para. 46(6)(b)(ii)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F44** Word in Sch. 5 para. 4.2 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 28 para. 46(6)(c)(i)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F45** Words in Sch. 5 para. 4.2 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 28 para. 46(6)(c)(ii)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F46** Word in Sch. 5 para. 4.2 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 28 para. 46(6)(c)(iii)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F47** Words in Sch. 5 para. 4.2 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 28 para. 46(6)(c)(iv)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F48** Words in Sch. 5 para. 4.3 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 28 para. 46(6)(d)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F49** Word in Sch. 5 para. 5 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 28 para. 46(7)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

SCHEDULE 6

Regulation 50

(Annex VI of the Directive) SUPPLEMENTARY REQUIREMENTS WHEN INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCTION TESTS SET OUT IN MODULE A1 IS USED (ARTICLE 24(2))

Commencement Information

I6 Sch. 6 in force at 3.8.2017, see [reg. 1](#)

Design and construction

On one or several watercrafts representing the production of the manufacturer one or more of the following tests, equivalent calculation or control shall be carried out by the manufacturer or on his behalf:

- (a) test of stability in accordance with point 3.2 of Part A of [F50Annex I][F50Schedule 1];
- (b) test of buoyancy characteristics in accordance with point 3.3 of Part A of [F50Annex I][F50Schedule 1].

Textual Amendments

F50 Words in Sch. 6 substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 28 para. 47\(a\)](#) (with [Sch. 28 para. 41](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

Noise emissions

For recreational craft fitted with inboard or stern drive engines without integral exhaust and for personal watercraft, on one or several watercraft representing the production of the watercraft manufacturer, the sound emission tests defined in Part C of [F50Annex I][F50Schedule 1] shall be carried out by the watercraft manufacturer, or on his behalf, under the responsibility of [F51a notified][F51an approved] body chosen by the manufacturer.

Textual Amendments

F51 Words in Sch. 6 substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 28 para. 47\(b\)](#) (with [Sch. 28 para. 41](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

For outboard engines and stern drive engines with integral exhaust, on one or several engines of each engine family representing the production of the engine manufacturer, the sound emission tests defined in Part C of [F50Annex I][F50Schedule 1] shall be carried out by the engine manufacturer, or on his behalf, under the responsibility of [F51a notified][F51an approved] body chosen by the manufacturer.

Where more than one engine of an engine family is tested, the statistical method described in [F52Annex VII][F52Schedule 7] shall be applied to ensure conformity of the sample.

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Textual Amendments

F52 Words in Sch. 6 substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 28 para. 47(c)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

SCHEDULE 7

Regulation 51

(Annex VII of the Directive)
**CONFORMITY OF PRODUCTION ASSESSMENT
 FOR EXHAUST AND NOISE EMISSIONS**

Commencement Information

I7 Sch. 7 in force at 3.8.2017, see [reg. 1](#)

1. For verifying the conformity of an engine family, a sample of engines shall be taken from the series. The manufacturer shall decide the size (n) of the sample, in agreement with the [F53 notified][F53 approved] body.
2. The arithmetical mean X of the results obtained from the sample shall be calculated for each regulated component of the exhaust and noise emission. The production of the series shall be deemed to conform to the requirements ('pass decision') if the following condition is met:

$$X + k \cdot S \leq L$$

S is standard deviation, where:

$$S^2 = \sum (x - X)^2 / (n - 1)$$

- X = the arithmetical mean of the results obtained from the sample
- x = the individual results obtained from the sample
- L = the appropriate limit value
- n = the number of engines in the sample
- k = statistical factor depending on n (see table below)

n	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
k	0,9730	,6130	,4890	,4210	,3760	,3420	,3170	,2960	,2790	,2650	,2530	,2420	,2330	,2240	,2160	,21	0,2030	,198

If n ≥ 20 then
 $k = 0,860 / \sqrt{n}$

Textual Amendments

F53 Word in [Sch. 7 para. 1](#) substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 28 para. 48** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

SCHEDULE 8

Regulation 52

(Annex VIII of the Directive)

SUPPLEMENTARY PROCEDURE TO BE APPLIED UNDER CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL (MODULE C)

Commencement Information

I8 Sch. 8 in force at 3.8.2017, see [reg. 1](#)

In the cases referred to in [^{F54}Article 24(5)][^{F54}regulation 52] when the quality level appears unsatisfactory, the following procedure shall apply:

Textual Amendments

F54 Words in Sch. 8 substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 28 para. 49\(a\)](#) (with [Sch. 28 para. 41](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

An engine is taken from the series and subjected to the test described in Part B of [^{F55}Annex I][^{F55}Schedule 1]. Test engines shall have been run in, partially or completely, in accordance with the manufacturer's specifications. If the specific exhaust emissions of the engine taken from the series exceed the limit values in accordance with Part B of [^{F55}Annex I][^{F55}Schedule 1], the manufacturer may ask for measurements to be done on a sample of engines taken from the series and including the engine originally taken. To ensure the conformity of the sample of engines with the requirements of [^{F56}this Directive][^{F56}these Regulations], the statistical method described in [^{F57}Annex VII][^{F57}Schedule 7] shall be applied.

Textual Amendments

F55 Words in Sch. 8 substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 28 para. 49\(b\)](#) (with [Sch. 28 para. 41](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

F56 Words in Sch. 8 substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 28 para. 49\(c\)](#) (with [Sch. 28 para. 41](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

F57 Words in Sch. 8 substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 28 para. 49\(d\)](#) (with [Sch. 28 para. 41](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

SCHEDULE 9

Regulation 9

(Annex IX of the Directive)

TECHNICAL DOCUMENTATION

Commencement Information

I9 Sch. 9 in force at 3.8.2017, see [reg. 1](#)

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The technical documentation [^{F58}referred to in Article 7(2) and Article 25] shall, as far as it is relevant for the assessment, contain the following:

- ((a)) A general description of the type;
- ((b)) Conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, and other relevant data;
- ((c)) Descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product;
- ((d)) A list of the standards referred to in [^{F59}Article 14][^{F59}regulation 41], applied in full or in part, and descriptions of the solutions adopted to fulfil the essential requirements when the standards referred to in [^{F59}Article 14][^{F59}regulation 41] have not been applied;
- ((e)) Results of design calculations made, examinations carried out and other relevant data;
- ((f)) Test reports, or calculations namely on stability in accordance with point 3.2 of Part A of [^{F60}Annex I][^{F60}Schedule 1] and on buoyancy in accordance with point 3.3 of Part A of [^{F60}Annex I][^{F60}Schedule 1];
- ((g)) Exhaust emissions test reports demonstrating compliance with Section 2 of Part B of [^{F60}Annex I][^{F60}Schedule 1];
- ((h)) Sound emissions test reports demonstrating compliance with Section 1 of Part C of [^{F60}Annex I][^{F60}Schedule 1].

Textual Amendments

- F58** Words in Sch. 9 omitted (E.W.S.) (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 28 para. 50(a)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F59** Words in Sch. 9 substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 28 para. 50(b)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F60** Words in Sch. 9 substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 28 para. 50(c)** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

SCHEDULE 10

Regulation 49

EU-type examination

^{F61}1. For the purposes of regulation 49, the conformity assessment carried out in accordance with Module B will be carried out in the manner set out in paragraphs 2, 3 and 4.

Textual Amendments

- F61** Sch. 10 omitted (E.W.S.) (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 28 para. 51** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I10 Sch. 10 para. 1 in force at 3.8.2017, see [reg. 1](#)

2. The conformity assessment must include an assessment of the adequacy of the technical design of the watercraft through examination of the technical documentation specified in paragraph 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the watercraft (combination of production type and design type).

Textual Amendments

F61 Sch. 10 omitted (E.W.S.) (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), [reg. 1](#), [Sch. 28 para. 51](#) (with [Sch. 28 para. 41](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

Commencement Information

I11 Sch. 10 para. 2 in force at 3.8.2017, see [reg. 1](#)

3. The conformity assessment must include an assessment of the adequacy of the following technical documentation—

- (a) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc;
- (b) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the watercraft;
- (c) a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
- (d) results of design calculations made, examinations carried out, etc.;
- (e) test reports; and
- (f) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards and/or technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on the manufacturer's behalf and under the manufacturer's responsibility.

Textual Amendments

F61 Sch. 10 omitted (E.W.S.) (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), [reg. 1](#), [Sch. 28 para. 51](#) (with [Sch. 28 para. 41](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

Commencement Information

I12 Sch. 10 para. 3 in force at 3.8.2017, see [reg. 1](#)

4. The technical documentation must include a general description of the watercraft.]

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Textual Amendments

F61 Sch. 10 omitted (E.W.S.) (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), [reg. 1](#), [Sch. 28 para. 51](#) (with [Sch. 28 para. 41](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

Commencement Information

I13 Sch. 10 para. 4 in force at 3.8.2017, see [reg. 1](#)

SCHEDULE 11

Regulation 2(1)

[^{F62}Requirements of notified bodies][^{F62}Requirements of approved bodies]

Textual Amendments

F62 Sch. 11 heading substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), [reg. 1](#), [Sch. 28 para. 52\(a\)](#) (with [Sch. 28 para. 41](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

1. A conformity assessment body must be established in the United Kingdom and have legal personality.

Commencement Information

I14 Sch. 11 para. 1 in force at 3.8.2017, see [reg. 1](#)

2. A conformity assessment body must be a third-party body independent of the organisation or the watercraft it assesses.

Commencement Information

I15 Sch. 11 para. 2 in force at 3.8.2017, see [reg. 1](#)

3. A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products which it assesses may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

Commencement Information

I16 Sch. 11 para. 3 in force at 3.8.2017, see [reg. 1](#)

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment must not be—

- (a) designer;
- (b) manufacturer;
- (c) supplier;

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- (d) installer;
- (e) purchaser;
- (f) owner;
- (g) user; or
- (h) maintainer

of the watercraft which the conformity assessment body assesses, nor the representative body of any of these persons.

Commencement Information

I17 Sch. 11 para. 4 in force at 3.8.2017, see [reg. 1](#)

5. Nothing in paragraph 4 of this Schedule will preclude the use of assessed products that are necessary for the operations of the conformity assessment body or the use of such products for personal purposes.

Commencement Information

I18 Sch. 11 para. 5 in force at 3.8.2017, see [reg. 1](#)

6. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment must not be directly involved in the—

- (a) design or manufacture;
- (b) marketing;
- (c) installation;
- (d) use or maintenance

of the watercraft, or represent the persons engaged in those activities.

Commencement Information

I19 Sch. 11 para. 6 in force at 3.8.2017, see [reg. 1](#)

7. A conformity assessment body must not engage in any activity, including consultancy services, that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are [^{F63}approved].

8. Conformity assessment bodies must ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

Commencement Information

I21 Sch. 11 para. 8 in force at 3.8.2017, see [reg. 1](#)

9. Conformity assessment bodies and their personnel must carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and be free from all pressures and inducements, particularly financial, which

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might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

Commencement Information

I22 Sch. 11 para. 9 in force at 3.8.2017, see [reg. 1](#)

10. A conformity assessment body must be capable of carrying out the conformity assessment tasks assigned to it by regulations 42 (applicable conformity assessment procedures) to 52 (conformity assessments carried out under module C (conformity to type based on internal production control)) and in relation to which it has been [^{F63}approved], whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

11. At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been [^{F63}approved], a conformity assessment body must have at its disposal, the necessary—

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment activities;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out ensuring the transparency and ability of reproduction of those procedures;
- (c) policies and procedures in place to distinguish between tasks that it carries out as [^{F64}an approved] body and other activities;
- (d) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the technology of the watercraft in question and the mass or serial nature of the production process; and
- (e) means to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and must have access to all necessary equipment and facilities to perform these activities.

12. The personnel responsible for carrying out the conformity assessment activities must have—

- (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been [^{F63}approved];
- (b) satisfactory knowledge of the requirements of the assessments that they carry out and adequate authority to carry out those assessments.

SCHEDULE 12

Regulation 2(1)

[^{F65}Operational requirements of notified bodies][^{F65}Operational requirements of approved bodies]

Textual Amendments

F65 Sch. 12 heading substituted (E.W.S) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), [reg. 1](#), [Sch. 28 para. 53\(a\)](#) (with [Sch. 28 para. 41](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

1. [^{F66}Approved] bodies must carry out conformity assessments in accordance with the conformity assessment procedures provided for in regulations 42 (applicable conformity assessment

procedures) to 52 (conformity assessments carried out under module C (conformity to type based on internal production control)).

2. Conformity assessments must be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators and private importers. Conformity assessment bodies must perform their activities taking due account of the size of an undertaking the sector in which it operates, its structure, the degree of complexity of the watercraft technology in question and the mass or serial nature of the production process.

Commencement Information

I27 Sch. 12 para. 2 in force at 3.8.2017, see [reg. 1](#)

3. Conformity assessment bodies must respect the degree of rigour and level of protection required for the compliance of the watercraft with ^{F67}[these Regulations].

4. Where ^{F68}[an approved] body finds that the requirements of regulation 6 (essential requirements) and Schedule 1 or the corresponding ^{F69}[designated] standards have not been met by the manufacturer or a private importer, that body must require that the manufacturer or private importer takes appropriate corrective measures and must not issue a conformity assessment certificate until the appropriate corrective measures have been taken.

5. Where, in the course of the monitoring of the conformity of the watercraft following the issue of a conformity assessment certificate, ^{F70}[an approved] body finds that a watercraft is no longer in compliance, it will require the manufacturer to take appropriate corrective measures and must suspend or withdraw the conformity assessment certificate if necessary.

6. Where corrective measures are not taken or do not have the required corrective effect, the ^{F71}[approved] body must restrict, suspend or withdraw any conformity assessment certificates as appropriate.

7.—(1) ^{F72}[An approved] body must inform the Secretary of State in writing of—

- (a) any refusal, restriction, suspension or withdrawal of a conformity assessment certificate;
- (b) any circumstances affecting the scope of and conditions for ^{F73}[approval]; and
- (c) any request for information which ^{F74}[the approved] body has received from a market surveillance authority regarding conformity assessment activities.

(2) ^{F75}[An approved] body must, following a request from the Secretary of State, inform the Secretary of State in writing of any conformity assessment activities performed within the scope of its ^{F73}[approval] provided under regulation 56 and any other activity performed, including cross-border activities and subcontracting.

8. ^{F76}[An approved] body must make provision in its contracts with its clients enabling such clients to appeal against a decision—

- (a) to refuse to issue a certificate of conformity or grant approval; and
- (b) to restrict, suspend or withdraw a certificate of conformity or approval.

9. ^{F77}[An approved] body must provide other bodies ^{F78}[approved] under these Regulations carrying on similar conformity assessment activities covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

10. ^{F79}[An approved] body must participate in the work of ^{F80}[any approved body coordination group established by the Secretary of State], directly or by means of its designated representatives.

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SCHEDULE 13

Regulation 67

Enforcement and investigatory powers conferred on the market surveillance authority

Enforcement powers under the 1987 Act

1. For the purposes of enforcing these Regulations, the following sections of the 1987 Act apply subject to the modifications in paragraph 2—

- (a) section 13 (prohibition notices and notices to warn);
- (b) section 14 (suspension notices);
- (c) section 16 (forfeiture: England and Wales and Northern Ireland);
- (d) section 17 (forfeiture: Scotland);
- (e) section 18 (power to obtain information);
- (f) section 19 (interpretation of Part II);
- (g) section 29 (powers of search etc);
- (h) section 30 (provisions supplemental to s 29);
- (i) section 31 (powers of customs officer to detain goods);
- (j) section 33 (appeals against detention of goods);
- (k) section 34 (compensation for seizure and detention);
- (l) section 35 (recovery of expenses of enforcement);
- (m) section 37 (power of Commissioners for Revenue and Customs);
- (n) section 42 (reports, etc.);
- (o) section 45 (interpretation);
- (p) section 46(1) (meaning of “supply”);
- (q) Schedule 2 (prohibition notices and notices to warn).

Commencement Information

I36 Sch. 13 para. 1 in force at 3.8.2017, see [reg. 1](#)

Modifications to the 1987 Act

2. The sections of the 1987 Act referred to in paragraph 1 are to apply as if—

- (a) in section 13—
 - (i) in subsection (1), for “unsafe” on each occasion that it appears, there were substituted “non-compliant”;
 - (ii) in subsection (1), “relevant” were omitted on each occasion that it appears;
 - (iii) in subsection (2), the words from “; and the Secretary of State may” to the end were omitted;
 - (iv) in subsection (4), the words “three months” were substituted for the words “six months;”
 - (v) subsections (5) to (7) were omitted;
- (b) in section 14—

- (i) in subsection (1), after “any safety provision has been contravened in relation to the goods”, there were inserted “or that such goods present a risk”;
 - (ii) in subsection (2)(b), after “a safety provision has been contravened in relation to the goods”, there were inserted “or that such goods present a risk”;
 - (iii) in subsection (2)(c), “under section 15 below” was omitted;
 - (iv) subsections (6) to (8) were omitted;
- (c) in section 16—
- (i) in subsection (1), after “a contravention in relation to the goods of a safety provision” there were inserted “or that such goods present a risk”;
 - (ii) in subsection (3), after “a contravention in relation to the goods of a safety provision” there were inserted “or that such goods present a risk”;
 - (iii) after subsection (4), there were inserted—
 - “(4A) A court may infer for the purposes of this section that any goods present a risk, if it is satisfied that such a risk is presented by goods which are representative of those goods (whether by reason of being of the same design or part of the same consignment or batch or otherwise).”;
- (d) in section 17—
- (i) in subsection (1), after “a contravention of a safety provision”, there were inserted “or where the goods present a risk”;
 - (ii) in subsection (6), after “a contravention in relation to those goods of a safety provision” there were inserted “or that those goods present a risk”;
 - (iii) after subsection (7), there were inserted—
 - “(7A) The Sheriff may infer for the purposes of this section that any goods present a risk, if satisfied that such a risk is presented by goods which are representative of those goods (whether by reason of being of the same design or part of the same consignment or batch or otherwise).”;
- (e) in section 18, subsections (3) and (4) were omitted;
- (f) in section 29—
- (i) in subsection (4)(a), after “any contravention of any safety provision in relation to the goods” there were inserted “or whether the goods present a risk”;
 - (ii) in subsection (4)(b), after “any such contravention” there were inserted “or whether the goods present a risk”;
- (g) in section 30—
- (i) at the end of subsection (2)(a)(ii), for “and” there were substituted “or”;
 - (ii) after subsection (2)(a)(ii), there were inserted—
 - “(iii) that any goods which any officer has power to inspect under section 29 are on any premises and their inspection is likely to demonstrate that they present a risk; and”;
 - (iii) subsections (5), (7) and (8) were omitted;
- (h) in section 31(1), for “Part II of this Act”, there were substituted “the 2017 Regulations”;
- (i) in section 34—
- (i) omit the word “and” at the end of subsection (1)(a); and
 - (ii) after that subsection, insert—

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- “(aa) the goods do not present a risk; and”;
- (j) in section 37(1), for “Part II of this Act”, there were substituted “the 2017 Regulations”;
- (k) in section 42—
- (i) subsections (1), (2) and (5) were omitted;
- (ii) in subsection (3)—
- (aa) the words from “and every person” to “section 27 above” were omitted; and
- (bb) the words “under that section or by that person by virtue of any such regulations” were substituted by “under the 2017 Regulations”;
- (l) in section 45(1)—
- (i) the definitions of “conditional sale agreement”, “gas”, “motor vehicle”, “personal injury”, “subordinate legislation” and “substance” were omitted;
- (ii) before the definition of “aircraft”, there were inserted—
- ““2017 Regulations” means the Recreational Craft Regulations 2017”;
- (iii) for the definition of “enforcing authority” there were substituted—
- ““enforcing authority” has the same meaning as in regulation 2(1) of the 2017 Regulations;”;
- (iv) for the definition of “goods” there were substituted—
- ““goods” means products or within the scope of the 2017 Regulations;”;
- (v) after the definition of “modifications” there were inserted—
- ““non-compliant” in relation to any goods means that—
- (a) a safety provision has been contravened in relation to the goods; or
- (b) the goods present a risk;”;
- (vi) after the definition of “premises”, there were inserted—
- ““present a risk” means present a risk within the meaning of “risk” set out in regulation 2(3) of the 2017 Regulations;”;
- (vii) for the definition of “safety provision” there were substituted—
- ““safety provision” means any provision of the 2017 Regulations”; and
- (viii) for the definition of “safety regulations” there were substituted—
- ““safety regulations” means the 2017 Regulations;”;
- (m) in section 46(1), omit “and, in relation to gas or water, those references shall be construed as including references to providing the service by which the gas or water is made available for use”; and
- (n) in Schedule 2—
- (i) for “unsafe”, on each occasion that it appears, there were substituted “non-compliant”; and
- (ii) for “safe”, on each occasion that it appears, there were substituted “not non-compliant”.

Commencement Information

I37 Sch. 13 para. 2 in force at 3.8.2017, see [reg. 1](#)

SCHEDULE 14

Regulation 67

Compliance notices, withdrawal notices and recall notices

Compliance notice

1. An enforcing authority may serve a compliance notice on a relevant economic operator in respect of a product if the authority has reasonable grounds for believing that there is non-compliance.

Commencement Information

I38 Sch. 14 para. 1 in force at 3.8.2017, see [reg. 1](#)

2. A compliance notice must—

- (a) require the relevant economic operator on which it is served to—
 - (i) end the non-compliance within such period as may be specified in the notice; or
 - (ii) provide evidence, within such period as may be specified in the notice, demonstrating to the satisfaction of the market surveillance authority that the non-compliance has not in fact occurred; and
- (b) warn the economic operator that, if the non-compliance persists or if satisfactory evidence has not been produced under sub-paragraph (a) within the period specified in the notice, further action may be taken in respect of the product or any product of the same type made available on the market by that relevant economic operator.

Commencement Information

I39 Sch. 14 para. 2 in force at 3.8.2017, see [reg. 1](#)

3. A compliance notice may include directions as to the measures to be taken by the economic operator to secure compliance, including different ways of securing compliance.

Commencement Information

I40 Sch. 14 para. 3 in force at 3.8.2017, see [reg. 1](#)

4. Subject to paragraph 5, an enforcing authority may revoke or vary a compliance notice by serving a notification on the economic operator.

Commencement Information

I41 Sch. 14 para. 4 in force at 3.8.2017, see [reg. 1](#)

5. An enforcing authority may not vary a compliance notice so as to make it more restrictive for the economic operator or more onerous for the economic operator to comply.

Commencement Information

I42 Sch. 14 para. 5 in force at 3.8.2017, see [reg. 1](#)

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Withdrawal notice

6. An enforcing authority may serve a withdrawal notice on a relevant economic operator in respect of product if the authority has reasonable grounds for believing that—

- (a) the product has been made available on the market; and
- (b) there is non-compliance.

Commencement Information

I43 Sch. 14 para. 6 in force at 3.8.2017, see [reg. 1](#)

7. A withdrawal notice must prohibit the relevant economic operator from making the product available on the market without the consent of the market surveillance authority.

Commencement Information

I44 Sch. 14 para. 7 in force at 3.8.2017, see [reg. 1](#)

8. A withdrawal notice may require the relevant economic operator to take action to alert end-users to any risk presented by the product.

Commencement Information

I45 Sch. 14 para. 8 in force at 3.8.2017, see [reg. 1](#)

9. A withdrawal notice may require the relevant economic operator to keep the enforcing authority informed of the whereabouts of any product referred to in the notice.

Commencement Information

I46 Sch. 14 para. 9 in force at 3.8.2017, see [reg. 1](#)

10. A consent given by the enforcing authority pursuant to a withdrawal notice may impose such conditions on the making available on the market of the product as the enforcing authority considers appropriate.

Commencement Information

I47 Sch. 14 para. 10 in force at 3.8.2017, see [reg. 1](#)

11. Subject to paragraph 7, an enforcing authority may revoke or vary a withdrawal notice by serving a notification on the economic operator.

Commencement Information

I48 Sch. 14 para. 11 in force at 3.8.2017, see [reg. 1](#)

12. An enforcing authority may not vary a withdrawal notice so as to make it more restrictive for the economic operator or more onerous for the economic operator to comply.

Commencement Information

I49 Sch. 14 para. 12 in force at 3.8.2017, see [reg. 1](#)

Recall notice

13. The enforcing authority may serve a recall notice on a relevant economic operator in respect of a product if the authority has reasonable grounds for believing that—

- (a) the product has been made available to end-users; and
- (b) there is non-compliance.

Commencement Information

I50 Sch. 14 para. 13 in force at 3.8.2017, see [reg. 1](#)

14. A recall notice must require the relevant economic operator to use reasonable endeavours to organise the return of the product from end-users to the relevant economic operator or another person specified in the notice.

Commencement Information

I51 Sch. 14 para. 14 in force at 3.8.2017, see [reg. 1](#)

15. A recall notice may—

- (a) require the recall to be effected in accordance with a code of practice;
- (b) require the relevant economic operator to—
 - (i) contact end-users in order to inform them of the recall, to the extent that it is practicable to do so;
 - (ii) publish a notice in such form and such manner as is likely to bring to the attention of end-users any risk the product poses and the fact of the recall; or
 - (iii) make arrangements for the collection or return of the product from end-users or its disposal; or
- (c) impose such additional requirements on the relevant economic operator as are reasonable and practicable with a view to achieving the return of the product.

Commencement Information

I52 Sch. 14 para. 15 in force at 3.8.2017, see [reg. 1](#)

16. In determining what requirements to include in a recall notice, the market surveillance authority must take into consideration the need to encourage distributors and end-users to contribute to its implementation.

Commencement Information

I53 Sch. 14 para. 16 in force at 3.8.2017, see [reg. 1](#)

17. A recall notice may only be issued by the market surveillance authority where—

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- (a) other action which it may require under these Regulations would not suffice to address the non-compliance;
- (b) the action being undertaken by the relevant economic operator is unsatisfactory or insufficient to address the non-compliance;
- (c) the market surveillance authority has given not less than 10 days' notice to the relevant economic operator of its intention to serve such a notice; and
- (d) the market surveillance authority has taken account of any advice obtained under paragraph 18.

Commencement Information

I54 Sch. 14 para. 17 in force at 3.8.2017, see [reg. 1](#)

18. A relevant economic operator which has received notice from the market surveillance authority of an intention to serve a recall notice may at any time prior to the service of the recall notice require the authority to seek the advice of such persons as the Institute determines on the questions of—

- (a) whether there is non-compliance; and
- (b) whether the issue of a recall notice would be proportionate.

Commencement Information

I55 Sch. 14 para. 18 in force at 3.8.2017, see [reg. 1](#)

19. Sub-paragraphs 17(b), (c) and (d) do not apply in the case of product presenting a serious risk requiring, in the view of the market surveillance authority, urgent action.

Commencement Information

I56 Sch. 14 para. 19 in force at 3.8.2017, see [reg. 1](#)

20. Where a relevant economic operator requires the enforcing authority to seek advice under paragraph 18, that relevant economic operator is to be responsible for the fees, costs and expenses of the Institute and of the person appointed by the Institute to advise the market surveillance authority.

Commencement Information

I57 Sch. 14 para. 20 in force at 3.8.2017, see [reg. 1](#)

21. In this Schedule, “Institute” means the charitable organisation with registered number 803725 and known as the Chartered Institute of Arbitrators.

Commencement Information

I58 Sch. 14 para. 21 in force at 3.8.2017, see [reg. 1](#)

22. A recall notice served by the market surveillance authority may require the relevant economic operator to keep the authority informed of the whereabouts of products to which the recall notice relates, so far as the relevant economic operator is able to do so.

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Commencement Information

I59 Sch. 14 para. 22 in force at 3.8.2017, see [reg. 1](#)

23. Subject to paragraph 24, a market surveillance authority may revoke or vary a recall notice by serving a notification on the economic operator.

Commencement Information

I60 Sch. 14 para. 23 in force at 3.8.2017, see [reg. 1](#)

24. A market surveillance authority may not vary a recall notice so as to make it more restrictive for the economic operator or more onerous for the economic operator to comply.

Commencement Information

I61 Sch. 14 para. 24 in force at 3.8.2017, see [reg. 1](#)

Interpretation

25. In this Schedule, “non-compliance” means that a product—

- (a) presents a risk; or
- (b) is not in conformity with Part 2 or RAMS (in its application to the product).

Commencement Information

I62 Sch. 14 para. 25 in force at 3.8.2017, see [reg. 1](#)

[^{F81}SCHEDULE 15

Regulations 42, 44 to 47, 50 to 52 and 54

Conformity assessment procedures

Textual Amendments

F81 Sch. 15 inserted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), [reg. 1](#), [Sch. 28 para. 54](#) (with [Sch. 28 para. 41](#)) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#))

MODULE A

Internal production control

Internal production control

1. Internal production control is the conformity assessment procedure whereby the manufacturer—

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- (a) fulfils the obligations set out in paragraphs 2 to 4; and
- (b) ensures and declares on the manufacturer's sole responsibility that the product concerned meets the essential requirements that apply to it.

Technical documentation

- 2.—(1) The manufacturer must draw up the technical documentation.
- (2) The technical documentation must—
- (a) make it possible to assess the product's conformity with the essential requirements that apply to it;
 - (b) include an adequate analysis and assessment of any risks;
 - (c) specify the essential requirements that apply to the product; and
 - (d) cover, as far as relevant for the assessment, the design, manufacture and operation of the product.
- (3) The technical documentation must contain, where applicable, at least the following—
- (a) a general description of the product;
 - (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies and circuits;
 - (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product;
 - (d) a list of the designated standards and other relevant technical specifications applied in full or in part (and where designated standards have been applied in part, the technical documentation must specify the parts which have been applied);
 - (e) where designated standards have not been applied, descriptions of the solutions adopted to meet the essential requirements;
 - (f) results of design calculations made and examinations carried out;
 - (g) test reports.

Manufacturing

3. The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured product with—
- (a) the technical documentation referred to in paragraph 2; and
 - (b) the essential requirements that apply to it.

UK marking and declaration of conformity

- 4.—(1) The manufacturer must affix the UK marking to each individual product that meets the essential requirements that apply to it.
- (2) The manufacturer must draw up a declaration of conformity for each product model and keep it together with the technical documentation at the disposal of the enforcing authority for 10 years after the product has been placed on the market. The declaration of conformity must identify the product model for which it has been drawn up.
- (3) The manufacturer must make a copy of the declaration of conformity available to the enforcing authority upon request.

MODULE A1

Internal production control plus supervised product testing

Internal production control plus supervised product testing

1. Internal production control plus supervised product testing is the conformity assessment procedure whereby the manufacturer—

- (a) fulfils the obligations set out in paragraphs 2 to 5; and
- (b) ensures and declares on the manufacturer's sole responsibility that the product concerned meets the essential requirements that apply to it.

Technical documentation

2.—(1) The manufacturer must draw up the technical documentation.

(2) The technical documentation must—

- (a) make it possible to assess the product's conformity with the essential requirements that apply to it;
- (b) include an adequate analysis and assessment of any risks;
- (c) specify the essential requirements that apply to the product; and
- (d) cover, as far as relevant for the assessment, the design, manufacture and operation of the product.

(3) The technical documentation must contain, where applicable, at least the following—

- (a) a general description of the product;
- (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies and circuits;
- (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product;
- (d) a list of the designated standards and other relevant technical specifications applied in full or in part (and where designated standards have been applied in part, the technical documentation must specify the parts which have been applied);
- (e) where designated standards have not been applied, descriptions of the solutions adopted to meet the essential requirements;
- (e) results of design calculations made and examinations carried out;
- (f) test reports.

Manufacturing

3. The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured product with—

- (a) the technical documentation referred to in paragraph 2; and
- (b) the essential requirements that apply to it.

Product checks

4.—(1) For each individual product manufactured, one or more tests on one or more specific aspects of the product must be carried out on the manufacturer's behalf in order to verify the product's conformity with the essential requirements that apply to it.

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(2) The tests must be carried out under the responsibility of an approved body chosen by the manufacturer.

(3) The manufacturer must, under the responsibility of the approved body, affix the approved body's identification number to the product during the manufacturing process.

UK marking and declaration of conformity

5.—(1) The manufacturer must affix the UK marking to each individual product that meets the essential requirements that apply to it.

(2) The manufacturer must draw up a declaration of conformity for each product model and keep it together with the technical documentation at the disposal of the enforcing authority for 10 years after the product has been placed on the market. The declaration of conformity must identify the product model for which it has been drawn up.

(3) The manufacturer must make a copy of the declaration of conformity available to the enforcing authority upon request.

MODULE B

Type examination

Type examination

1. Type examination is the part of a conformity assessment procedure in which an approved body—

- (a) examines the technical design of a product; and
- (b) verifies and attests that the technical design of the product meets the essential requirements that apply to it.

How type examination must be carried out, etc.

2.—(1) The conformity assessment procedure must include an assessment of the adequacy of the technical design of the product through examination of the technical documentation and supporting evidence referred to in paragraph 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the product (combination of production type and design type).

(2) The assessment referred to in sub-paragraph (1) may cover several versions of the product if—

- (a) the differences between the versions of the product do not affect the level of safety and the other requirements concerning the performance of the product; and
- (b) the different versions of the product are referred to in the corresponding type examination certificate, if necessary by means of amendments to the original certificate.

Application for type examination

3.—(1) The manufacturer must lodge an application for type examination with a single approved body of the manufacturer's choice.

(2) The application must include—

- (a) the name and address of the manufacturer and, if the application is lodged by an authorised representative, the name and address of the authorised representative;
- (b) a declaration that the same application has not been lodged with any other approved body;

- (c) the technical documentation;
 - (d) the specimens representative of the production envisaged; and
 - (e) the supporting evidence for the adequacy of the technical design solution.
- (3) The manufacturer must, if requested by the approved body, provide further specimens if needed for carrying out the test programme.
- (4) The technical documentation referred to in sub-paragraph (2)(c) must—
- (a) make it possible to assess the product's conformity with the essential requirements that apply to it;
 - (b) include an adequate analysis and assessment of any risks;
 - (c) specify the essential requirements that apply to the product; and
 - (d) cover, as far as relevant for the assessment, the design, manufacture and operation of the product.
- (5) The technical documentation referred to in sub-paragraph (2)(c) must contain, where applicable, at least the following—
- (a) a general description of the product;
 - (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies and circuits;
 - (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product;
 - (d) a list of the designated standards and other relevant technical specifications applied in full or in part (and where designated standards have been applied in part, the technical documentation must specify the parts which have been applied);
 - (e) where designated standards have not been applied, descriptions of the solutions adopted to meet the essential requirements;
 - (f) results of design calculations made and examinations carried out;
 - (g) test reports.
- (5) The supporting evidence for the adequacy of the technical design solution referred to in sub-paragraph (2)(e) must—
- (a) mention any documents that have been used, in particular where the relevant designated standards or technical specifications have not been applied in full; and
 - (b) include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on the manufacturer's behalf and under the manufacturer's responsibility.

Examination, etc. by approved body

4.—(1) The approved body must examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the product.

- (2) The approved body must—
- (a) verify that the specimen has been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant designated standards or technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards or specifications;

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- (b) carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant designated standards or technical specifications, these have been applied correctly;
- (c) carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant designated standards or technical specifications have not been applied, the solutions adopted by the manufacturer meet the essential requirements covered by the standards or specifications; and
- (d) agree with the manufacturer on a location where the examinations and tests will be carried out.

Evaluation report

5. The approved body must draw up an evaluation report that records the activities undertaken in accordance with paragraph 4 and their outcomes. Without prejudice to its obligations vis-à-vis the Secretary of State, the approved body may release the content of the report, in full or in part, only with the agreement of the manufacturer.

Type examination certificate

6.—(1) Where the type meets the essential requirements that apply to the product concerned, the approved body must issue a type examination certificate to the manufacturer.

(2) The certificate (which may have one or more annexes attached) must contain—

- (a) the name and address of the manufacturer;
- (b) the conclusions of the examination;
- (c) the conditions (if any) for its validity;
- (d) the necessary data for identification of the approved type; and
- (e) all relevant information to allow the conformity of manufactured products with the examined type to be evaluated and to allow for in-service control.

(3) Where the type does not meet the essential requirements that apply to the product concerned, the approved body must refuse to issue a type examination certificate and must inform the applicant accordingly, giving detailed reasons for its refusal.

Changes

7.—(1) The approved body must keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the essential requirements that apply to the product concerned and must determine whether such changes require further investigation. If so, the approved body must inform the manufacturer accordingly.

(2) The manufacturer must inform the approved body that holds the technical documentation relating to the type examination certificate of all modifications to the approved type that may affect the conformity of the product with the essential requirements that apply to it or the conditions for validity of the certificate. Such modifications require additional approval in the form of an addition to the original type examination certificate.

Approved body's duties in respect of type examination certificates

8.—(1) The approved body must inform the Secretary of State about the type examination certificates and any additions thereto which it has issued or withdrawn and must, periodically or upon request, make available to the Secretary of State a list of certificates and any additions thereto refused, suspended or otherwise restricted.

(2) The approved body must inform the other approved bodies about the type examination certificates and any additions thereto which it has refused, withdrawn, suspended or otherwise restricted and, upon request, about such certificates and additions thereto which it has issued.

(3) The approved body must, on request, provide the Secretary of State and other approved bodies with a copy of the type examination certificates and additions thereto which it has issued.

(4) The approved body must, on request, provide the Secretary of State with a copy of the technical documentation and the results of the examinations carried out by the approved body.

(5) The approved body must keep a copy of the type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

Manufacturer's duties in respect of type examination certificates

9. The manufacturer must keep a copy of the type examination certificate, its annexes and additions together with the technical documentation at the disposal of the enforcing authority for 10 years after the product has been placed on the market.

MODULE C

Conformity to type based on internal production control

Conformity to type based on internal production control

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer—

- (a) fulfils the obligations set out in paragraphs 2 and 3; and
- (b) ensures and declares that the product concerned is in conformity with the type described in the type examination certificate and meets the essential requirements that apply to it.

Manufacturing

2. The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured product with—

- (a) the approved type described in the type examination certificate; and
- (b) the essential requirements that apply to it.

UK marking and declaration of conformity

3.—(1) The manufacturer must affix the UK marking to each individual product that is in conformity with the type described in the type examination certificate and meets the essential requirements that apply to it.

(2) The manufacturer must draw up a declaration of conformity for each product model and keep it at the disposal of the enforcing authority for 10 years after the product has been placed on the market. The declaration of conformity must identify the product model for which it has been drawn up.

(3) The manufacturer must make a copy of the declaration of conformity available to the enforcing authority upon request.

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MODULE C1

Conformity to type based on internal production control plus supervised product testing

Conformity to type based on internal production control plus supervised product testing

1. Conformity to type based on internal production control plus supervised product testing is the part of a conformity assessment procedure whereby the manufacturer—

- (a) fulfils the obligations set out in paragraphs 2 to 4; and
- (b) ensures and declares on the manufacturer's sole responsibility that the product concerned—
 - (i) is in conformity with the type described in the type examination certificate; and
 - (ii) meets the essential requirements that apply to it.

Manufacturing

2. The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured product with—

- (a) the type described in the type examination certificate; and
- (b) the essential requirements that apply to it.

Product checks

3.—(1) For each individual product manufactured, one or more tests on one or more specific aspects of the product must be carried out on the manufacturer's behalf in order to verify the product's conformity with the essential requirements that apply to it.

(2) The tests must be carried out under the responsibility of an approved body chosen by the manufacturer.

(3) The manufacturer must, under the responsibility of the approved body, affix the approved body's identification number to the product during the manufacturing process.

UK marking and declaration of conformity

4.—(1) The manufacturer must affix the UK marking to each individual product that is in conformity with the type described in the type examination certificate and meets the essential requirements that apply to it.

(2) The manufacturer must draw up a declaration of conformity for each product model and keep it at the disposal of the enforcing authority for 10 years after the product has been placed on the market. The declaration of conformity must identify the product model for which it has been drawn up.

(3) The manufacturer must make a copy of the declaration of conformity available to the enforcing authority upon request.

MODULE D

Conformity to type based on quality assurance of the production process

Conformity to type based on quality assurance of the production process

1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer—

- (a) fulfils the obligations set out in paragraphs 2 and 5; and
- (b) ensures and declares on the manufacturer's sole responsibility that the product concerned—
 - (i) is in conformity with the type described in the type examination certificate; and
 - (ii) meets the essential requirements that apply to it.

Manufacturing

2. The manufacturer—

- (a) must operate an approved quality system for production, final product inspection and testing of the products concerned as specified in paragraph 3; and
- (b) is subject to surveillance as specified in paragraph 4.

Quality system

3.—(1) The manufacturer must lodge an application for assessment of the manufacturer's quality system with the approved body of the manufacturer's choice for the products concerned.

(2) The application must include—

- (a) 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;
- (b) a declaration that the same application has not been lodged with any other approved body;
- (c) all relevant information for the product category envisaged;
- (d) the documentation concerning the quality system;
- (e) the technical documentation of the approved type and a copy of the type examination certificate.

(3) The quality system must ensure that the products—

- (a) are in conformity with the type described in the type examination certificate; and
- (b) meet the essential requirements that apply to them.

(4) All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions.

(5) The quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records and must, in particular, contain an adequate description of—

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

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- (c) the examinations and tests that will be carried out before, during and after manufacture and the frequency with which they will be carried out;
 - (d) the quality records, such as inspection reports and test data, calibration data and qualification reports on the personnel concerned; and
 - (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.
- (6) The approved body must assess the quality system to determine whether it satisfies the requirements referred to in sub-paragraph (3). The approved body must presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant designated standard or technical specification.
- (7) For the purpose of the assessment referred to in sub-paragraph (6), the approved body must ensure that—
- (a) in addition to experience in quality management systems, the auditing team has at least one member with experience of evaluation in the relevant product field and product technology concerned and knowledge of the essential requirements that apply to the products;
 - (b) the audit includes an assessment visit to the manufacturer's premises; and
 - (c) the auditing team reviews the technical documentation referred to in sub-paragraph (2)(e) to verify the manufacturer's ability to identify the essential requirements that apply to the products and to carry out the necessary examinations with a view to ensuring compliance of the products with those requirements.
- (8) The approved body must notify its decision on whether the quality system satisfies the requirements referred to in sub-paragraph (3) to the manufacturer. The notification must contain the conclusions of the audit and the approved body's reasoned assessment.
- (9) The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
- (10) The manufacturer must keep the approved body that approved the quality system informed of any intended change to the quality system, and if so informed, the approved body must evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in sub-paragraph (3) or whether a reassessment is necessary.
- (11) The approved body must notify the manufacturer of its decision. The notification must contain the conclusions of the examination and the approved body's reasoned assessment.

Surveillance under the responsibility of the approved body

- 4.—(1) The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- (2) The manufacturer must, for assessment purposes, allow the approved body access to the manufacture, inspection, testing and storage sites and must provide it with all necessary information, in particular—
- (a) the quality system documentation;
 - (b) the quality records, such as inspection reports and test data, calibration data, and qualification reports on the personnel concerned.
- (3) The approved body must carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and must provide the manufacturer with an audit report.
- (4) In addition, the approved body may pay unexpected visits to the manufacturer. During such visits the approved body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The approved body must provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

UK marking and declaration of conformity

5.—(1) The manufacturer must affix the UK marking and, under the responsibility of the approved body referred to in paragraph 3(1), the approved body's identification number to each individual product that is in conformity with the type described in the type examination certificate and meets the essential requirements that apply to it.

(2) The manufacturer must draw up a declaration of conformity for each product model and keep it at the disposal of the enforcing authority for 10 years after the product has been placed on the market. The declaration of conformity must identify the product model for which it has been drawn up.

(3) The manufacturer must make a copy of the declaration of conformity available to the enforcing authority upon request.

Manufacturer's duty to keep application, etc.

6. The manufacturer must, for a period ending at least 10 years after the product has been placed on the market, keep at the disposal of the enforcing authority—

- (a) a copy of the application referred to in paragraph 3(1) including the information and documentation referred to in paragraph 3(2);
- (b) documents relating to any change to the quality system referred to in paragraph 3(10), as approved by the approved body;
- (c) the decisions and reports of the approved body referred to in paragraphs 3(11) and 4(3) and (4).

Approved body's duties in respect of quality system approvals

7.—(1) Each approved body must inform the Secretary of State of quality system approvals issued or withdrawn and must, periodically or upon request, make available to the Secretary of State a list of quality system approvals refused, suspended or otherwise restricted.

(2) Each approved body must inform the other approved bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

MODULE E

Conformity to type based on product quality assurance

Conformity to type based on product quality assurance

1. Conformity to type based on product quality assurance is that part of a conformity assessment procedure whereby the manufacturer—

- (a) fulfils the obligations set out in paragraphs 2 and 5; and
- (b) ensures and declares on the manufacturer's sole responsibility that the product concerned—
 - (i) is in conformity with the type described in the type examination certificate; and
 - (ii) meets the essential requirements that apply to it.

Manufacturing

2. The manufacturer—

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- (a) must operate an approved quality system for final product inspection and testing of the products concerned as specified in paragraph 3; and
- (b) is subject to surveillance as specified in paragraph 4.

Quality system

3.—(1) The manufacturer must lodge an application for assessment of the manufacturer's quality system with the approved body of the manufacturer's choice for the products concerned.

(2) The application must include—

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, the authorised representative's name and address;
- (b) a declaration that the same application has not been lodged with any other approved body;
- (c) all relevant information for the product category envisaged;
- (d) the documentation concerning the quality system; and
- (e) the technical documentation of the approved type and a copy of the type examination certificate.

(3) The quality system must ensure that the products—

- (a) are in conformity with the type described in the type examination certificate; and
- (b) meet the essential requirements that apply to them.

(4) All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions.

(5) The quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records and must, in particular, contain an adequate description of—

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- (b) the examinations and tests that will be carried out after manufacture;
- (c) the quality records, such as inspection reports and test data, calibration data and qualification reports on the personnel concerned; and
- (d) the means of monitoring the effective operation of the quality system.

(6) The approved body must assess the quality system to determine whether it satisfies the requirements referred to in sub-paragraph (3). The approved body must presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant designated standard or technical specification.

(7) For the purpose of the assessment referred to in sub-paragraph (6), the approved body must ensure that—

- (a) in addition to experience in quality management systems, the auditing team has at least one member with experience of evaluation in the relevant product field and product technology concerned and knowledge of the essential requirements that apply to the products;
- (b) the audit includes an assessment visit to the manufacturer's premises; and
- (c) the auditing team reviews the technical documentation referred to in sub-paragraph (2)(e) to verify the manufacturer's ability to identify the essential requirements that apply to the products and to carry out the necessary examinations with a view to ensuring compliance of the products with those requirements.

(8) The approved body must notify its decision on whether the quality system satisfies the requirements referred to in sub-paragraph (3) to the manufacturer. The notification must contain the conclusions of the audit and the approved body's reasoned assessment.

(9) The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

(10) The manufacturer must keep the approved body that approved the quality system informed of any intended change to the quality system, and if so informed, the approved body must evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in sub-paragraph (3) or whether a reassessment is necessary.

(11) The approved body must notify the manufacturer of its decision. The notification must contain the conclusions of the examination and the approved body's reasoned assessment.

Surveillance under the responsibility of the approved body

4.—(1) The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

(2) The manufacturer must, for assessment purposes, allow the approved body access to the manufacture, inspection, testing and storage sites and must provide it with all necessary information, in particular—

- (a) the quality system documentation;
- (b) the quality records, such as inspection reports and test data, calibration data and qualification reports on the personnel concerned.

(3) The approved body must carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and must provide the manufacturer with an audit report.

(4) In addition, the approved body may pay unexpected visits to the manufacturer. During such visits the approved body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The approved body must provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

UK marking and declaration of conformity

5.—(1) The manufacturer must affix the UK marking and, under the responsibility of the approved body referred to in paragraph 3(1), the approved body's identification number to each individual product that is in conformity with the type described in the type examination certificate and meets the essential requirements that apply to it.

(2) The manufacturer must draw up a declaration of conformity for each product model and keep it at the disposal of the enforcing authority for 10 years after the product has been placed on the market. The declaration of conformity must identify the product model for which it has been drawn up.

(3) The manufacturer must make a copy of the declaration of conformity available to the enforcing authority upon request.

Manufacturer's duty to keep application, etc.

6. The manufacturer must, for a period ending at least 10 years after the product has been placed on the market, keep at the disposal of the enforcing authority—

- (a) a copy of the application referred to in paragraph 3(1) including the information and documentation referred to in paragraph 3(2);

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- (b) documents relating to any change to the quality system referred to in paragraph 3(10), as approved by the approved body;
- (c) the decisions and reports of the approved body referred to in paragraphs 3(11) and 4(3) and (4).

Approved body's duties in respect of quality system approvals

7.—(1) Each approved body must inform the Secretary of State of quality system approvals issued or withdrawn and must, periodically or upon request, make available to the Secretary of State the list of quality system approvals refused, suspended or otherwise restricted.

(2) Each approved body must inform the other approved bodies of quality system approvals which it has refused, suspended or withdrawn and, upon request, of quality system approvals which it has issued.

MODULE F

Conformity to type based on product verification

Conformity to type based on product verification

1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer—

- (a) fulfils the obligations set out in paragraphs 2, 5(1) and 6; and
- (b) ensures and declares on the manufacturer's sole responsibility that the product concerned, which has been subject to the provisions of paragraph 3—
 - (i) is in conformity with the type described in the type examination certificate; and
 - (ii) meets the essential requirements that apply to it.

Manufacturing

2. The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured product with—

- (a) the approved type described in the type examination certificate; and
- (b) the essential requirements that apply to it.

Verification

3.—(1) An approved body chosen by the manufacturer must carry out appropriate examinations and tests in order to check the conformity of the product with—

- (a) the approved type described in the type examination certificate; and
- (b) the essential requirements that apply to it.

(2) The examinations and tests to check the conformity of the products with the essential requirements that apply to it must be carried out, at the choice of the manufacturer, either by—

- (a) examination and testing of every product as specified in paragraph 4; or
- (b) examination and testing of the products on a statistical basis as specified in paragraph 5.

Verification of conformity by examination and testing of every product

4.—(1) All products must be individually examined, and appropriate tests set out in the relevant designated standard or technical specifications or equivalent tests must be carried out in order to verify conformity with the approved type described in the type examination certificate and with the essential requirements that apply to it. In the absence of such a designated standard, the approved body concerned must decide on the appropriate tests to be carried out.

(2) The approved body must issue a certificate of conformity in respect of the examinations and tests carried out and must affix its identification number to each approved product or have it affixed under its responsibility.

(3) The manufacturer must keep the certificates of conformity at the disposal of the enforcing authority for 10 years after the product has been placed on the market.

Statistical verification of conformity

5.—(1) The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of each lot produced and must present the manufacturer's products for verification in the form of homogeneous lots.

(2) A random sample must be taken from each lot by the approved body. All products in a sample must be individually examined, and appropriate tests set out in the relevant designated standard or technical specification or equivalent tests must be carried out in order to ensure their conformity with the essential requirements that apply to them and to determine whether the lot is to be accepted or rejected. In the absence of such a designated standard, the approved body concerned must decide on the appropriate tests to be carried out.

(3) If a lot is accepted, all products of the lot must be considered approved, except for those products from the sample that have been found not to satisfy the tests.

(4) The approved body must issue a certificate of conformity in respect of the examinations and tests carried out and must affix its identification number to each approved product or have it affixed under its responsibility.

(5) The manufacturer must keep the certificates of conformity at the disposal of the enforcing authority for 10 years after the product has been placed on the market.

(6) If a lot is rejected, the approved body or, if the approved body fails to do so, the Secretary of State must take appropriate measures to prevent that lot being placed on the market. In the event of the frequent rejection of lots, the approved body may suspend the statistical verification and take appropriate measures.

UK marking and declaration of conformity

6.—(1) The manufacturer must affix the UK marking and, under the responsibility of the approved body referred to in paragraph 3, the approved body's identification number to each individual product that is in conformity with the approved type described in the type examination certificate and meets the essential requirements that apply to it.

(2) The manufacturer must draw up a declaration of conformity for each product model and keep it at the disposal of the enforcing authority for 10 years after the product has been placed on the market. The declaration of conformity must identify the product model for which it has been drawn up.

(3) The manufacturer must make a copy of the declaration of conformity available to the enforcing authority upon request.

(4) If the approved body referred to in paragraph 3 agrees and under its responsibility, the manufacturer may also affix the approved body's identification number to the product.

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Affixing of approved body's identification number during manufacturing process

7. If the approved body agrees and under its responsibility, the manufacturer may affix the approved body's identification number to the product during the manufacturing process.

Authorised representative

8. Where the manufacturer appoints an authorised representative (see regulation 39), the obligations in paragraphs 2 and 5(1) must not form part of the authorised representative's mandate.

MODULE G

Conformity based on unit verification

Conformity based on unit verification

1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer—

- (a) fulfils the obligations set out in paragraphs 2, 3 and 5; and
- (b) ensures and declares on the manufacturer's sole responsibility that the product concerned, which has been subject to the provisions of paragraph 4, meets the essential requirements that apply to it.

Technical documentation

2.—(1) The manufacturer must draw up the technical documentation and make it available to the approved body referred to in paragraph 4.

(2) The technical documentation must—

- (a) make it possible to assess the product's conformity with the essential requirements that apply to it;
- (b) include an adequate analysis and assessment of the risks;
- (c) specify the essential requirements that apply to the product; and
- (d) cover, as far as relevant for the assessment, the design, manufacture and operation of the product.

(3) The technical documentation must contain, where applicable, at least the following—

- (a) a general description of the product;
- (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies and circuits;
- (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product;
- (d) a list of the designated standards and other relevant technical specifications, applied in full or in part (and where designated standards have been applied in part, the technical documentation must specify the parts which have been applied);
- (e) where designated standards have not been applied, descriptions of the solutions adopted to meet the essential requirements;
- (f) results of design calculations made and examinations carried out;
- (g) test reports.

(4) The manufacturer must keep the technical documentation at the disposal of the enforcing authority for 10 years after the product has been placed on the market.

Manufacturing

3. The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured product with the essential requirements that apply to it.

Verification

4.—(1) An approved body chosen by the manufacturer must carry out appropriate examinations and tests, set out in the relevant designated standard or technical specification or equivalent tests, to check the conformity of the product with the essential requirements that apply to it or have them carried out. In the absence of such a designated standard or technical specification the approved body concerned must decide on the appropriate tests to be carried out.

(2) The approved body must issue a certificate of conformity in respect of the examinations and tests carried out and must affix its identification number to the approved product or have it affixed under its responsibility.

(3) The manufacturer must keep the certificates of conformity at the disposal of the enforcing authority for 10 years after the product has been placed on the market.

UK marking and declaration of conformity

5.—(1) The manufacturer must affix the UK marking and, under the responsibility of the approved body referred to in paragraph 4, the approved body's identification number to each product that meets the essential requirements that apply to it.

(2) The manufacturer must draw up a declaration of conformity and keep it at the disposal of the enforcing authority for 10 years after the product has been placed on the market. The declaration of conformity must identify the product for which it has been drawn up.

(3) The manufacturer must make a copy of the declaration of conformity available to the enforcing authority upon request.

MODULE H

Conformity based on full quality assurance

Conformity based on full quality assurance

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer—

- (a) fulfils the obligations set out in paragraphs 2 and 5; and
- (b) ensures and declares on the manufacturer's sole responsibility that the product concerned meets the essential requirements that apply to it.

Manufacturing

2. The manufacturer—

- (a) must operate an approved quality system for design, manufacture and final product inspection and testing of the product concerned as specified in paragraph 3; and

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- (b) is subject to surveillance as specified in paragraph 4.

Quality system

3.—(1) The manufacturer must lodge an application for assessment of the manufacturer's quality system with the approved body of the manufacturer's choice for the product concerned.

(2) The application must include—

- (a) 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;
- (b) the technical documentation for one model of each category of products intended to be manufactured, which must contain, where applicable, at least the following—
 - (i) a general description of the product;
 - (ii) conceptual design and manufacturing drawings and schemes of components, sub-assemblies and circuits;
 - (iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product;
 - (iv) a list of the designated standards and other relevant technical specifications applied in full or in part (and where designated standards have been applied in part, the technical documentation must specify the parts which have been applied);
 - (v) where designated standards have not been applied, descriptions of the solutions adopted to meet the essential requirements;
 - (vi) results of design calculations made and examinations carried out;
 - (vii) test reports;
- (c) the documentation concerning the quality system; and
- (d) a declaration that the same application has not been lodged with any other approved body.

(3) The quality system must ensure that the products meet the essential requirements that apply to them.

(4) All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions.

(5) The quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records and must, in particular, contain an adequate description of—

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;
- (b) the technical design specifications, including standards, that will be applied and, where the relevant designated standards or technical specifications will not be applied in full, the means that will be used to ensure that the essential requirements that apply to the products will be met;
- (c) the design control and design verification techniques, processes and systematic actions that will be used when designing the products pertaining to the product category covered;
- (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- (e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

- (f) the quality records, such as inspection reports and test data, calibration data and qualification reports on the personnel concerned;
 - (g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.
- (6) The approved body must assess the quality system to determine whether it satisfies the requirements referred to in sub-paragraph (3). The approved body must presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant designated standard or technical specification.
- (7) For the purpose of the assessment referred to in sub-paragraph (6), the approved body must ensure that—
- (a) in addition to experience in quality management systems, the auditing team has at least one member experienced as an assessor in the relevant product field and product technology concerned, and knowledge of the essential requirements that apply to the products;
 - (b) the audit includes an assessment visit to the manufacturer's premises; and
 - (c) the auditing team reviews the technical documentation referred to sub-paragraph (2)(b) to verify the manufacturer's ability to identify the essential requirements that apply to the products and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.
- (8) The approved body must notify the manufacturer or the manufacturer's authorised representative of its decision on whether the quality system satisfies the requirements referred to in sub-paragraph (3). The notification must contain the conclusions of the audit and the approved body's reasoned assessment.
- (9) The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
- (10) The manufacturer must keep the approved body that approved the quality system informed of any intended change to the quality system, and if so informed, the approved body must evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in sub-paragraph (3) or whether a reassessment is necessary.
- (11) The approved body must notify the manufacturer of its decision. The notification must contain the conclusions of the examination and the approved body's reasoned assessment.

Surveillance under the responsibility of the approved body

- 4.—(1) The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- (2) The manufacturer must, for assessment purposes, allow the approved body access to the design, manufacture, inspection, testing and storage sites and must provide it with all necessary information, in particular—
- (a) the quality system documentation;
 - (b) the quality records as provided for by the design part of the quality system, such as results of analyses, calculations and tests; and
 - (c) the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data and qualification reports on the personnel concerned.
- (3) The approved body must carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and must provide the manufacturer with an audit report.
- (4) In addition, the approved body may pay unexpected visits to the manufacturer. During such visits, the approved body may, if necessary, carry out product tests, or have them carried out, in

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order to verify that the quality system is functioning correctly. The approved body must provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

UK marking and declaration of conformity

5.—(1) The manufacturer must affix the UK marking and, under the responsibility of the approved body referred to in paragraph 3(1), the approved body's identification number to each individual product that meets the essential requirements that apply to it.

(2) The manufacturer must draw up a declaration of conformity for each product model and keep it at the disposal of the enforcing authority for 10 years after the product has been placed on the market. The declaration of conformity must identify the product model for which it has been drawn up.

(3) The manufacturer must make a copy of the declaration of conformity available to the enforcing authority upon request.

Manufacturer's duty to keep application, etc.

6. The manufacturer must, for a period ending at least 10 years after the product has been placed on the market, keep at the disposal of the enforcing authority—

- (a) the technical documentation referred to in paragraph 3(2)(b);
- (b) the documentation concerning the quality system referred to in paragraph 3(2)(c);
- (c) documents relating to any change to the quality system referred to in paragraph 3(10), as approved by the approved body;
- (d) the decisions and reports of the approved body referred to in paragraphs 3(11) and 4(3) and (4).

Approved body's duties in respect of quality system approvals

7.—(1) Each approved body must inform the Secretary of State of quality system approvals issued or withdrawn and must, periodically or upon request, make available to the Secretary of State the list of quality system approvals refused, suspended or otherwise restricted.

(2) Each approved body must inform the other approved bodies of quality system approvals which it has refused, suspended or withdrawn and, upon request, of quality system approvals which it has issued.]

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Changes and effects yet to be applied to :

- Sch. 11 para. 1 substituted by [S.I. 2024/504 reg. 14](#)
- reg. 2(1) words omitted by [S.I. 2024/696 reg. 19\(2\)](#)
- reg. 2(1) words substituted by [S.I. 2019/696 Sch. 28 para. 2\(2\)\(d\)](#) (This amendment not applied to legislation.gov.uk. Sch. 28 para. 2(2)(d) omitted immediately before IP completion day by virtue of S.I. 2020/1460, reg. 1(4), Sch. 3 para. 3)
- reg. 2(1) words substituted by [S.I. 2019/696 Sch. 28 para. 2\(2\)\(o\)](#) (This amendment not applied to legislation.gov.uk. Sch. 28 para. 2(2)(o) substituted immediately before IP completion day by S.I. 2020/676, regs. 1(1), 4(16)(a))
- reg. 2(1) words substituted by [S.I. 2019/696 Sch. 28 para. 2\(2\)\(r\)](#) (This amendment not applied to legislation.gov.uk. Sch. 28 para. 2(2)(r) substituted immediately before IP completion day by S.I. 2020/676, regs. 1(1), 4(16)(b))
- reg. 2(1) words substituted by [S.I. 2019/696 Sch. 28 para. 2\(2\)\(t\)](#) (This amendment not applied to legislation.gov.uk. Sch. 28 para. 2(2)(t) substituted immediately before IP completion day by S.I. 2020/676, regs. 1(1), 4(16)(c))
- reg. 2(1) words substituted in earlier amending provision S.I. 2019/696, Sch. 28 para. 2(2)(d) by [S.I. 2020/852 reg. 4\(2\) Sch. 1 para. 1\(q\)\(i\)](#) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 1(q)(i) omitted immediately before it comes into force by virtue of S.I. 2020/1460, regs. 1(3), Sch. 4 para. 1(3))
- reg. 4(1)(g) words substituted by [S.I. 2019/696 Sch. 28 para. 4](#) (This amendment not applied to legislation.gov.uk. Sch. 28 para. 4 substituted immediately before IP completion day by virtue of S.I. 2020/1460, reg. 1(4), Sch. 3 para. 20(3))
- reg. 40A(8) words substituted by [S.I. 2024/696 reg. 19\(3\)](#)
- reg. 40C substituted by [S.I. 2024/696 reg. 19\(4\)](#)
- reg. 54 word substituted by [S.I. 2019/696 Sch. 28 para. 35\(b\)](#) (This amendment not applied to legislation.gov.uk. Sch. 28 para. 35(b) substituted immediately before IP completion day by virtue of S.I. 2020/1460, reg. 1(4), Sch. 3 para. 20(6)(a))
- reg. 89A(4)-(8) omitted by [S.I. 2024/696 reg. 19\(5\)](#)