


Apple Inc.

### Regulatory Registration Information






Regulatory registration information for Taiwan, Japan, and China are excluded from this list as the country specific IFU contains all necessary information.

- a. Cardiac Health Application
- b. Women's Health

#### a. Cardiac Health Application

Feature version/ Regulatory Registration Information	ECG V1	ECG V2	IRNF V1	IRNF V2	Afib History
US	 Apple Inc. One Apple Park Way Cupertino, CA 95014 <a href="http://www.apple.com">www.apple.com</a> Apple Distribution International Hollyhill Industrial Estate, Hollyhill, Cork, Ireland <b>Contact:</b> <a href="mailto:medicalcompliance@group.apple.com">medicalcompliance@group.apple.com</a>				

Apple Inc.

Feature version/ Regulatory Registration Information	ECG V1	ECG V2	IRNF V1	IRNF V2	Afib History
<p>EU</p>	<div data-bbox="415 337 541 386" style="border: 1px solid black; padding: 2px; display: inline-block;">EC REP</div> <p>Apple Distribution International Hollyhill Industrial Estate, Hollyhill, Cork, Ireland</p> <p>Contact: <a href="mailto:medicalcompliance@group.apple.com">medicalcompliance@group.apple.com</a></p> <div data-bbox="415 638 594 727" style="border: 1px solid black; padding: 5px; display: inline-block;">  </div>	<div data-bbox="716 337 842 386" style="border: 1px solid black; padding: 2px; display: inline-block;">EC REP</div> <p>Apple Distribution International Hollyhill Industrial Estate, Hollyhill, Cork, Ireland</p> <p>Contact: <a href="mailto:medicalcompliance@group.apple.com">medicalcompliance@group.apple.com</a></p> <div data-bbox="716 638 894 727" style="border: 1px solid black; padding: 5px; display: inline-block;">  </div> <div data-bbox="716 760 835 833" style="border: 2px solid black; padding: 5px; display: inline-block; margin-top: 10px;"> <b>MD</b> </div>	<div data-bbox="1016 337 1142 386" style="border: 1px solid black; padding: 2px; display: inline-block;">EC REP</div> <p>Apple Distribution International Hollyhill Industrial Estate, Hollyhill, Cork, Ireland</p> <p>Contact: <a href="mailto:medicalcompliance@group.apple.com">medicalcompliance@group.apple.com</a></p> <div data-bbox="1016 638 1194 727" style="border: 1px solid black; padding: 5px; display: inline-block;">  </div>	<div data-bbox="1316 337 1442 386" style="border: 1px solid black; padding: 2px; display: inline-block;">EC REP</div> <p>Apple Distribution International Hollyhill Industrial Estate, Hollyhill, Cork, Ireland</p> <p>Contact: <a href="mailto:medicalcompliance@group.apple.com">medicalcompliance@group.apple.com</a></p> <div data-bbox="1316 638 1495 727" style="border: 1px solid black; padding: 5px; display: inline-block;">  </div> <div data-bbox="1316 760 1436 833" style="border: 2px solid black; padding: 5px; display: inline-block; margin-top: 10px;"> <b>MD</b> </div>	<div data-bbox="1617 337 1743 386" style="border: 1px solid black; padding: 2px; display: inline-block;">EC REP</div> <p>Apple Distribution International Hollyhill Industrial Estate, Hollyhill, Cork, Ireland</p> <p>Contact: <a href="mailto:medicalcompliance@group.apple.com">medicalcompliance@group.apple.com</a></p> <div data-bbox="1617 638 1795 727" style="border: 1px solid black; padding: 5px; display: inline-block;">  </div> <div data-bbox="1617 760 1736 833" style="border: 2px solid black; padding: 5px; display: inline-block; margin-top: 10px;"> <b>MD</b> </div>
<p><b>AUSTRALIA AND TERRITORIES (CHRISTMAS ISLAND, COCOS (KEELING) ISLANDS, HEARD AND MCDONALD ISLANDS, NORFOLK ISLAND)</b></p>	<p>Not Available</p>	<p>Sponsor Details:</p> <p>Apple Pty Ltd Level 3, 20 Martin Place Sydney NSW 2000 Australia <a href="https://www.apple.com/au/">https://www.apple.com/au/</a> TEL: 1-300-321-456</p>			


Feature version/ Regulatory Registration Information	ECG V1	ECG V2	IRNF V1	IRNF V2	Afib History
<b>BRAZIL</b>	<p>ANVISA Nº: 80117580880</p> <p>RESPONSÁVEL TÉCNICO: LUIZ LEVY CRUZ MARTINS – CRF-SP: 42415</p> <p>DETENTOR DA NOTIFICAÇÃO:</p> <p>Emergo Brazil Import Importação e Distribuição de Produtos Médicos Hospitalares Ltda. Avenida Francisco Matarazzo, 1.752, Salas 502/503, Água Branca, São Paulo-SP, CEP – 05001-200 CNPJ: 04.967.408/0001-98 E-mail: <a href="mailto:brazilvigilance@ul.com">brazilvigilance@ul.com</a></p>	<p>ANVISA Nº: 80117580880</p> <p>RESPONSÁVEL TÉCNICO: LUIZ LEVY CRUZ MARTINS – CRF-SP: 42415</p> <p>DETENTOR DA NOTIFICAÇÃO:</p> <p>Emergo Brazil Import Importação e Distribuição de Produtos Médicos Hospitalares Ltda. Avenida Francisco Matarazzo, 1.752, Salas 502/503, Água Branca, São Paulo-SP, CEP – 05001-200 CNPJ: 04.967.408/0001-98 E-mail: <a href="mailto:brazilvigilance@ul.com">brazilvigilance@ul.com</a></p>	<p>ANVISA Nº: 80117580881</p> <p>RESPONSÁVEL TÉCNICO: LUIZ LEVY CRUZ MARTINS – CRF-SP: 42415</p> <p>DETENTOR DA NOTIFICAÇÃO:</p> <p>Emergo Brazil Import Importação e Distribuição de Produtos Médicos Hospitalares Ltda. Avenida Francisco Matarazzo, 1.752, Salas 502/503, Água Branca, São Paulo-SP, CEP – 05001-200 CNPJ: 04.967.408/0001-98 E-mail: <a href="mailto:brazilvigilance@ul.com">brazilvigilance@ul.com</a></p>	<p>ANVISA Nº: 80117580881</p> <p>RESPONSÁVEL TÉCNICO: LUIZ LEVY CRUZ MARTINS – CRF-SP: 42415</p> <p>DETENTOR DA NOTIFICAÇÃO:</p> <p>Emergo Brazil Import Importação e Distribuição de Produtos Médicos Hospitalares Ltda. Avenida Francisco Matarazzo, 1.752, Salas 502/503, Água Branca, São Paulo-SP, CEP – 05001-200 CNPJ: 04.967.408/0001-98 E-mail: <a href="mailto:brazilvigilance@ul.com">brazilvigilance@ul.com</a></p>	<p>ANVISA Nº: 80117581018</p> <p>RESPONSÁVEL TÉCNICO: LUIZ LEVY CRUZ MARTINS – CRF-SP: 42415</p> <p>DETENTOR DA NOTIFICAÇÃO:</p> <p>Emergo Brazil Import Importação e Distribuição de Produtos Médicos Hospitalares Ltda. Avenida Francisco Matarazzo, 1.752, Salas 502/503, Água Branca, São Paulo-SP, CEP – 05001-200 CNPJ: 04.967.408/0001-98 E-mail: <a href="mailto:brazilvigilance@ul.com">brazilvigilance@ul.com</a></p>
<b>COLOMBIA</b>	<p>PRODUCTO: Software de Electrografía y aplicación de ECG para software de análisis de fotopletismografía</p> <p>IMPORTADOR:</p> <p>IMPOMED S.A.S Calle 1 SUR NO. 77A-21 Interior 201 Medellin Colombia</p> <p>REGISTRO SANITARIO NO.: INVIMA 2020DM-0021828</p>	<p>PRODUCTO: Software de Electrografía y aplicación de ECG para software de análisis de fotopletismografía</p> <p>IMPORTADOR:</p> <p>IMPOMED S.A.S Calle 1 SUR NO. 77A-21 Interior 201 Medellin Colombia</p> <p>REGISTRO SANITARIO NO.: INVIMA 2020DM-0021828</p>	<p>PRODUCTO: Función de notificación de ritmo irregular (IRNF por sus siglas en ingles)</p> <p>IMPORTADOR:</p> <p>IMPOMED S.A.S Calle 1 SUR NO. 77A-21 Interior 201 Medellin Colombia</p> <p>REGISTRO SANITARIO NO.: INVIMA 2020DM-0021835</p>	<p>PRODUCTO: Función de notificación de ritmo irregular (Version 2.X)</p> <p>IMPORTADOR:</p> <p>IMPOMED S.A.S Calle 1 SUR NO. 77A-21 Interior 201 Medellin Colombia</p> <p>REGISTRO SANITARIO NO.: INVIMA 2020DM-0021835</p>	<p>PRODUCTO: Funcion de Historial de Fibrilación Auricular</p> <p>IMPORTADOR:</p> <p>IMPOMED S.A.S Calle 1 SUR NO. 77A-21 Interior 201 Medellin Colombia</p> <p>REGISTRO SANITARIO NO.: INVIMA 2022DM-0026135</p>
<b>INDIA</b>	<p>Import License Number: IMP/MD/2022/000754</p> <p>IMPORTER:</p> <p>Asia Actual India (OPC) Pvt. Ltd. 523A, Tower A, Spaze I-Tech Park, Sector 49, Gurgaon, Haryana, India</p>	<p>Import License Number: IMP/MD/2022/000754</p> <p>IMPORTER:</p> <p>Asia Actual India (OPC) Pvt. Ltd. 523A, Tower A, Spaze I-Tech Park, Sector 49, Gurgaon, Haryana, India</p>	<p>Import License Number: IMP/MD/2022/000754</p> <p>IMPORTER:</p> <p>Asia Actual India (OPC) Pvt. Ltd. 523A, Tower A, Spaze I-Tech Park, Sector 49, Gurgaon, Haryana, India</p>	<p>Import License Number: IMP/MD/2022/000754</p> <p>IMPORTER:</p> <p>Asia Actual India (OPC) Pvt. Ltd. 523A, Tower A, Spaze I-Tech Park, Sector 49, Gurgaon, Haryana, India</p>	<p>Import License Number: IMP/MD/2022/000754</p> <p>IMPORTER:</p> <p>Asia Actual India (OPC) Pvt. Ltd. 523A, Tower A, Spaze I-Tech Park, Sector 49, Gurgaon, Haryana, India</p>

Feature version/ Regulatory Registration Information	ECG V1	ECG V2	IRNF V1	IRNF V2	Afib History
<b>INDONESIA</b>	Not Available	Product License Number: KEMENKES RI AKL 20502121822  REGISTRANT:  PT. ASIA ACTUAL INDONESIA, DKI Jakarta Gandaria 8 Office Tower, Unit 6J. Jl. Sultan Iskandar Muda Jakarta Selatan 12240 – Indonesia +62 (021) 2930-3747	Product License Number: KEMENKES RI AKL 20502121725  REGISTRANT:  PT. ASIA ACTUAL INDONESIA, DKI Jakarta Gandaria 8 Office Tower, Unit 6J. Jl. Sultan Iskandar Muda Jakarta Selatan 12240 – Indonesia +62 (021) 2930-3747	Product License Number: KEMENKES RI AKL 20502220301  REGISTRANT:  PT. ASIA ACTUAL INDONESIA, DKI Jakarta Gandaria 8 Office Tower, Unit 6J. Jl. Sultan Iskandar Muda Jakarta Selatan 12240 – Indonesia +62 (021) 2930-3747	Product License Number: KEMENKES RI AKL 20502220325  REGISTRANT:  PT. ASIA ACTUAL INDONESIA, DKI Jakarta Gandaria 8 Office Tower, Unit 6J. Jl. Sultan Iskandar Muda Jakarta Selatan 12240 – Indonesia +62 (021) 2930-3747
<b>ISRAEL</b>  <b>AMAR REGISTRATION HOLDER</b>	<b>AMAR REGISTRATION HOLDER:</b>  Medogar Medical Equipment Ltd. Hasadna St. 8 P.O.B 2586 Ra'annana 4365104 ISRAEL Office Tel: +972-9-7401457 Fax:+972-9-7401459  מדוגר מכשור רפואי בע"מ הסדנא 8 ת.ד. 2566 רעננה 4365104 טל: 09-7401457 פקס: 09-7401459  מידוגר للأجهزة الطبية المحدودة شارع هاسادنا 8, ص.ب. 2566 رعنانا 4365104  <a href="http://www.medogar.co.il">www.medogar.co.il</a> <a href="mailto:info@medogar.co.il">info@medogar.co.il</a>  <b>AMAR Certificate Number:</b> 21080016	<b>AMAR REGISTRATION HOLDER:</b>  Medogar Medical Equipment Ltd. Hasadna St. 8 P.O.B 2586 Ra'annana 4365104 ISRAEL Office Tel: +972-9-7401457 Fax:+972-9-7401459  מדוגר מכשור רפואי בע"מ הסדנא 8 ת.ד. 2566 רעננה 4365104 טל: 09-7401457 פקס: 09-7401459  מידוגר للأجهزة الطبية المحدودة شارع هاسادنا 8, ص.ب. 2566 رعنانا 4365104  <a href="http://www.medogar.co.il">www.medogar.co.il</a> <a href="mailto:info@medogar.co.il">info@medogar.co.il</a>  <b>AMAR Certificate Number:</b> 21080016	<b>AMAR REGISTRATION HOLDER:</b>  Medogar Medical Equipment Ltd. Hasadna St. 8 P.O.B 2586 Ra'annana 4365104 ISRAEL Office Tel: +972-9-7401457 Fax:+972-9-7401459  מדוגר מכשור רפואי בע"מ הסדנא 8 ת.ד. 2566 רעננה 4365104 טל: 09-7401457 פקס: 09-7401459  מידוגר للأجهزة الطبية المحدودة شارع هاسادنا 8, ص.ب. 2566 رعنانا 4365104  <a href="http://www.medogar.co.il">www.medogar.co.il</a> <a href="mailto:info@medogar.co.il">info@medogar.co.il</a>  <b>AMAR Certificate Number:</b> 21080017	<b>AMAR REGISTRATION HOLDER:</b>  Medogar Medical Equipment Ltd. Hasadna St. 8 P.O.B 2586 Ra'annana 4365104 ISRAEL Office Tel: +972-9-7401457 Fax:+972-9-7401459  מדוגר מכשור רפואי בע"מ הסדנא 8 ת.ד. 2566 רעננה 4365104 טל: 09-7401457 פקס: 09-7401459  מידוגר للأجهزة الطبية المحدودة شارع هاسادنا 8, ص.ب. 2566 رعنانا 4365104  <a href="http://www.medogar.co.il">www.medogar.co.il</a> <a href="mailto:info@medogar.co.il">info@medogar.co.il</a>  <b>AMAR Certificate Number:</b> 21080018	<b>AMAR REGISTRATION HOLDER:</b>  Medogar Medical Equipment Ltd. Hasadna St. 8 P.O.B 2586 Ra'annana 4365104 ISRAEL Office Tel: +972-9-7401457 Fax:+972-9-7401459  מדוגר מכשור רפואי בע"מ הסדנא 8 ת.ד. 2566 רעננה 4365104 טל: 09-7401457 פקס: 09-7401459  מידוגר للأجهزة الطبية المحدودة شارع هاسادنا 8, ص.ب. 2566 رعنانا 4365104  <a href="http://www.medogar.co.il">www.medogar.co.il</a> <a href="mailto:info@medogar.co.il">info@medogar.co.il</a>  <b>AMAR Certificate Number:</b> 21080020

Apple Inc.

Feature version/ Regulatory Registration Information	ECG V1	ECG V2	IRNF V1	IRNF V2	Afib History
<b>MALAYSIA</b>	Not Available	<p>Product License/MDA Reg No.: GB7992021-54025</p> <p>AUTHORIZED REPRESENTATIVE:</p> <p>Nyprax Business Solutions No 12, Lorong Teknologi B, Nouvelle Industrial Park, Taman Sains Selangor 1, Kota Damansara, PJU 5, 47810 Petaling Jaya, Selangor, Malaysia</p> <p>Email: <a href="mailto:kenna@nyprax.com">kenna@nyprax.com</a> Tel: +6012 620 1824</p>	<p>Product License/MDA Reg No.: GB7830421-55921</p> <p>AUTHORIZED REPRESENTATIVE:</p> <p>Nyprax Business Solutions No 12, Lorong Teknologi B, Nouvelle Industrial Park, Taman Sains Selangor 1, Kota Damansara, PJU 5, 47810 Petaling Jaya, Selangor, Malaysia</p> <p>Email: <a href="mailto:kenna@nyprax.com">kenna@nyprax.com</a> Tel: +6012 620 1824</p>	<p>Product License/MDA Reg No.: GB7830421-55921</p> <p>AUTHORIZED REPRESENTATIVE:</p> <p>Nyprax Business Solutions No 12, Lorong Teknologi B, Nouvelle Industrial Park, Taman Sains Selangor 1, Kota Damansara, PJU 5, 47810 Petaling Jaya, Selangor, Malaysia</p> <p>Email: <a href="mailto:kenna@nyprax.com">kenna@nyprax.com</a> Tel: +6012 620 1824</p>	<p>Product License/MDA Reg No.: GB5330222-102051</p> <p>AUTHORIZED REPRESENTATIVE:</p> <p>Nyprax Business Solutions No 12, Lorong Teknologi B, Nouvelle Industrial Park, Taman Sains Selangor 1, Kota Damansara, PJU 5, 47810 Petaling Jaya, Selangor, Malaysia</p> <p>Email: <a href="mailto:kenna@nyprax.com">kenna@nyprax.com</a> Tel: +6012 620 1824</p>
<b>MOLDOVA</b>	Not Available	<p>Registration Number: DM000322299, DM000322300</p> <p>AUTHORIZED REPRESENTATIVE:</p> <p>JERELO S.R.L. MD-2024, str. Pietrăriei, nr 19A, of. 3. mun. Chişinău, Republica Moldova +37378538295</p>	<p>Registration Number: DM000322301, DM000322302</p> <p>AUTHORIZED REPRESENTATIVE:</p> <p>JERELO S.R.L. MD-2024, str. Pietrăriei, nr 19A, of. 3. mun. Chişinău, Republica Moldova +37378538295</p>	<p>Registration Number: DM000322301, DM000322302</p> <p>AUTHORIZED REPRESENTATIVE:</p> <p>JERELO S.R.L. MD-2024, str. Pietrăriei, nr 19A, of. 3. mun. Chişinău, Republica Moldova +37378538295</p>	<p>Registration Number: DM000322299, DM000322300</p> <p>AUTHORIZED REPRESENTATIVE:</p> <p>JERELO S.R.L. MD-2024, str. Pietrăriei, nr 19A, of. 3. mun. Chişinău, Republica Moldova +37378538295</p>
<b>PERU</b>	<p>Registro Sanitario N° :DB5982E</p> <p>IMPORTADOR:</p> <p>Drogería Emergo Peru S.R.L. Calle Las Orquídeas Nro. 585, Int. 1301, San Isidro, Lima, Perú RUC: 205 52 75 65 34</p>	<p>Registro Sanitario N° :DB5982E</p> <p>IMPORTADOR:</p> <p>Drogería Emergo Peru S.R.L. Calle Las Orquídeas Nro. 585, Int. 1301, San Isidro, Lima, Perú RUC: 205 52 75 65 34</p>	<p>Registro Sanitario N° :DB6240E</p> <p>IMPORTADOR:</p> <p>Drogería Emergo Peru S.R.L. Calle Las Orquídeas Nro. 585, Int. 1301, San Isidro, Lima, Perú RUC: 205 52 75 65 34</p>	<p>Registro Sanitario N° :DB6240E</p> <p>IMPORTADOR:</p> <p>Drogería Emergo Peru S.R.L. Calle Las Orquídeas Nro. 585, Int. 1301, San Isidro, Lima, Perú RUC: 205 52 75 65 34</p>	<p>Registro Sanitario N° :DB7939E</p> <p>IMPORTADOR:</p> <p>Drogería Emergo Peru S.R.L. Calle Las Orquídeas Nro. 585, Int. 1301, San Isidro, Lima, Perú RUC: 205 52 75 65 34</p>


Feature version/ Regulatory Registration Information	ECG V1	ECG V2	IRNF V1	IRNF V2	Afib History
<p><b>REPUBLIC OF KOREA</b></p>	<p>본 앱은 "의료기기" 임.</p> <p>수입업자: 이머고코리아 (유) 06236) 서울특별시 강남구 테헤란로 152 강남파이낸스센터 26층 제조원: Apple Inc. (본사) One Apple Park Way, Cupertino, CA 95014, USA (공장) 20450 Stevens Creek Blvd., Cupertino, CA 95014, USA</p> <p>허가번호: 수허 20-177 호</p> <p>명칭 (제품명, 품목명, 모델명): 심전도 앱, 심전계, ECG App 소프트웨어 버전: 1.X 출시연월: 2020년 11월 포장단위: 1ea</p> <p>사용목적 : 모바일플랫폼(Apple Watch)에 장착된 심전도(ECG)센서를 이용하여 측정된 단일유도(Lead I) 유사심전도 신호로부터 심방세동 또는 정상박동 존재 여부를 판정함으로써, 심전도 신호를 생성, 기록, 저장, 전송 및 표시하는 의료용 어플리케이션.</p>	<p>본 앱은 "의료기기" 임.</p> <p>수입업자: 이머고코리아 (유) 06236) 서울특별시 강남구 테헤란로 152 강남파이낸스센터 26층 제조원: Apple Inc. (본사) One Apple Park Way, Cupertino, CA 95014, USA (공장) 20450 Stevens Creek Blvd., Cupertino, CA 95014, USA</p> <p>허가번호: 수허 20-177 호</p> <p>명칭 (제품명, 품목명, 모델명): 심전도 앱, 심전계, ECG App 소프트웨어 버전: 2.X 출시연월: 2022년 01월 포장단위: 1ea</p> <p>사용목적 : 모바일플랫폼(Apple Watch)에 장착된 심전도(ECG)센서를 이용하여 측정된 단일유도(Lead I) 유사심전도 신호로부터 심방세동 또는 정상박동 존재 여부를 판정함으로써, 심전도 신호를 생성, 기록, 저장, 전송 및 표시하는 의료용 어플리케이션.</p>	<p>본 기능은 "의료기기" 임.</p> <p>수입업자: 이머고코리아 (유) 06236) 서울특별시 강남구 테헤란로 152 강남파이낸스센터 26층 제조원: Apple Inc. (본사) One Apple Park Way, Cupertino, CA 95014, USA (공장) 20450 Stevens Creek Blvd., Cupertino, CA 95014, USA</p> <p>허가번호: 수허 20-176 호</p> <p>명칭 (제품명, 품목명, 모델명): 불규칙한 박동 알림 기능, 휴대형심전도분석 소프트웨어, Irregular Rhythm Notification Feature (IRNF) 소프트웨어 버전: 1.X 출시연월: 2020년 11월 포장단위: 1ea</p> <p>사용목적: 모바일 플랫폼(Apple Watch)에 장착된 광혈류측정(PPG) 센서를 통해 맥박을 측정·분석하여 심방세동으로 의심되는 불규칙한 심장박동을 확인하고 사용자에게 알림을 보내는 의료용 어플리케이션이다.</p>	<p>본 앱은 "의료기기" 임.</p> <p>수입업자: 이머고코리아 (유) 06236) 서울특별시 강남구 테헤란로 152 강남파이낸스센터 26층 제조원: Apple Inc. (본사) One Apple Park Way, Cupertino, CA 95014, USA (공장) 20450 Stevens Creek Blvd., Cupertino, CA 95014, USA</p> <p>허가번호: 수허 20-176 호</p> <p>명칭 (제품명, 품목명, 모델명): 불규칙한 박동 알림 기능, 휴대형심전도분석 소프트웨어, Irregular Rhythm Notification Feature (IRNF) 소프트웨어 버전: 2.X 출시연월: 2022년 12월 포장단위: 1ea</p> <p>사용목적: 모바일 플랫폼(Apple Watch)에 장착된 광혈류측정(PPG) 센서를 통해 맥박을 측정·분석하여 심방세동으로 의심되는 불규칙한 심장박동을 확인하고 사용자에게 알림을 보내는 의료용 어플리케이션이다.</p>	<p>본 앱은 "의료기기" 임.</p> <p>수입업자: 이머고코리아 (유) 06236) 서울특별시 강남구 테헤란로 152 강남파이낸스센터 26층 제조원: Apple Inc. (본사) One Apple Park Way, Cupertino, CA 95014, USA (공장) 20450 Stevens Creek Blvd., Cupertino, CA 95014, USA</p> <p>허가번호: 수허 23-138 호</p> <p>명칭 (제품명, 품목명, 모델명): 휴대형 심전도분석소프트웨어, AFHF, Atrial Fibrillation History Feature (AFHF) 소프트웨어 버전: 1.X 출시연월: 2023년 7월 포장단위: 1ea</p> <p>사용목적: 심방세동(AF)을 진단받은 만 22세 이상의 사용자를 대상으로 모바일플랫폼 (스마트워치, Apple Watch)에 장착된 광혈류측정(PPG) 센서를 이용하여 맥박을 측정·분석하여 심방세동으로 의심되는 불규칙한 심장박동을 식별하고, Apple Watch 착용시간(7일) 동안에 심방세동 징후를 보인 시간 비율을 표시하고 기록하는 앱</p>

Feature version/ Regulatory Registration Information	ECG V1	ECG V2	IRNF V1	IRNF V2	Afib History
<b>SWITZERLAND</b>	<b>CH-REP:</b>  QUNIQUE GmbH Bahnhofweg 17 5610 Wohlen Switzerland				
<b>THAILAND</b>	Medical Device License Number: 64-2-2-2-0004085  IMPORTER:  บริษัท เอเชีย แอคซิว (ประเทศไทย) จำกัด 8 อาคารทีวัน ห้องเลขที่ 15-102 ชั้น 15 ซอยสุขุมวิท 40 ถนนสุขุมวิท แขวงพระโขนง เขตคลองเตย กรุงเทพฯ 10110 โทร. 02-821-5998	Medical Device License Number: 64-2-2-2-0004085  IMPORTER:  บริษัท เอเชีย แอคซิว (ประเทศไทย) จำกัด 8 อาคารทีวัน ห้องเลขที่ 15-102 ชั้น 15 ซอยสุขุมวิท 40 ถนนสุขุมวิท แขวงพระโขนง เขตคลองเตย กรุงเทพฯ 10110 โทร. 02-821-5998	Medical Device License Number: 64-2-2-2-0002928  IMPORTER:  บริษัท เอเชีย แอคซิว (ประเทศไทย) จำกัด 8 อาคารทีวัน ห้องเลขที่ 15-102 ชั้น 15 ซอยสุขุมวิท 40 ถนนสุขุมวิท แขวงพระโขนง เขตคลองเตย กรุงเทพฯ 10110 โทร. 02-821-5998	Medical Device License Number: 65-2-2-2-0016259  IMPORTER:  บริษัท เอเชีย แอคซิว (ประเทศไทย) จำกัด 8 อาคารทีวัน ห้องเลขที่ 15-102 ชั้น 15 ซอยสุขุมวิท 40 ถนนสุขุมวิท แขวงพระโขนง เขตคลองเตย กรุงเทพฯ 10110 โทร. 02-821-5998	Medical Device License Number: 65-2-2-2-0015185  IMPORTER:  บริษัท เอเชีย แอคซิว (ประเทศไทย) จำกัด 8 อาคารทีวัน ห้องเลขที่ 15-102 ชั้น 15 ซอยสุขุมวิท 40 ถนนสุขุมวิท แขวงพระโขนง เขตคลองเตย กรุงเทพฯ 10110 โทร. 02-821-5998
<b>TURKEY</b>	Apple Teknoloji ve Satış Limited Şirketi Büyükdere Caddesi Levent 199 Kat:22-23 34394 Şişli İstanbul Türkiye				
<b>UKRAINE</b>	ТОВ «ДЖЕРЕЛО-УКРАЇНА» 01033, Україна, м. Київ, вулиця Шота Руставелі 33-Б, офіс 27 e-mail: <a href="mailto:uarep@jerele.eu">uarep@jerele.eu</a> тел. +38 (044) 360 30 11   UA.TR.120				

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Feature version/ Regulatory Registration Information	ECG V1	ECG V2	IRNF V1	IRNF V2	Afib History
<b>VIETNAM</b>	Product License Number: 220002518/PCBB-HCM  REGISTRANT:  Asia Actual Vietnam Co., LTD. 45/90 Binh Tien, Ward 7, District 6, Ho Chi Minh City, Vietnam  +84 969159420	Product License Number: 220002519/PCBB-HCM  REGISTRANT:  Asia Actual Vietnam Co., LTD. 45/90 Binh Tien, Ward 7, District 6, Ho Chi Minh City, Vietnam  +84 969159420	Product License Number: 220002520/PCBB-HCM  REGISTRANT:  Asia Actual Vietnam Co., LTD. 45/90 Binh Tien, Ward 7, District 6, Ho Chi Minh City, Vietnam  +84 969159420	Product License Number: 220002521/PCBB-HCM  REGISTRANT:  Asia Actual Vietnam Co., LTD. 45/90 Binh Tien, Ward 7, District 6, Ho Chi Minh City, Vietnam  +84 969159420	Product License Number: 220003108/PCBB-HCM  REGISTRANT:  Asia Actual Vietnam Co., LTD. 45/90 Binh Tien, Ward 7, District 6, Ho Chi Minh City, Vietnam  +84 969159420

b. Women’s Health (US and EU required languages)


Feature version/ Regulatory Registration Information	CT
<b>US</b>	 <p>           Apple Inc.            One Apple Park Way Cupertino, CA 95014  <a href="http://www.apple.com">www.apple.com</a>            Apple Distribution International Hollyhill Industrial Estate,            Hollyhill, Cork,            Ireland  <b>Contact:</b> <a href="mailto:medicalcompliance@group.apple.com">medicalcompliance@group.apple.com</a> </p>



# Apple Inc.

Feature version/ Regulatory Registration Information	CT
<p><b>EU</b></p>	<div data-bbox="653 298 779 345" style="border: 1px solid black; padding: 2px; display: inline-block; margin-bottom: 10px;"> <span style="border: 1px solid black; padding: 2px 5px;">EC</span> <span style="border: 1px solid black; padding: 2px 5px; margin-left: 5px;">REP</span> </div> <p>Apple Distribution International Hollyhill Industrial Estate, Hollyhill, Cork, Ireland</p> <p>Contact: <a href="mailto:medicalcompliance@group.apple.com">medicalcompliance@group.apple.com</a></p> <div data-bbox="653 553 758 639" style="text-align: center; margin-top: 20px;">  </div>
<p><b>ISRAEL</b></p>	<p>Medogar Medical Equipment Ltd. Hasadna St. 8 P.O.B 2586 Ra'annana 4365104 ISRAEL Office Tel: +972-9-7401457 Fax: +972-9-7401459</p> <p style="text-align: right;">מדוגר מכשור רפואי בע"מ הסדנא 8 ת.ד. 2566 רעננה 4365104 טל: 09-7401457 פקס: 09-7401459</p> <p style="text-align: right;">מידוגאר للأجهزة الطبية المحدودة شارع هاسادنا 8، ص.ب. 2566 رعنانا 4365104</p> <p><a href="http://www.medogar.co.il">www.medogar.co.il</a> <a href="mailto:info@medogar.co.il">info@medogar.co.il</a></p> <p><b>AMAR Certificate Number:</b> 21080019</p>
<p><b>MOLDOVA</b></p>	<p>AUTHORIZED REPRESENTATIVE:</p> <p>JERELO S.R.L. MD-2024, str. Pietrăriei, nr 19A, of. 3. mun. Chişinău, Republica Moldova +37378538295</p>
<p><b>SWITZERLAND</b></p>	<p><b>CH-REP:</b></p> <p>QUNIQUE GmbH Bahnhofweg 17 5610 Wohlen Switzerland</p>

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Feature version/ Regulatory Registration Information	CT
UKRAINE	<p>ТОВ «ДЖЕРЕЛО-УКРАЇНА» 01033, Україна, м. Київ, вулиця Шота Руставелі 33-Б, офіс 27 e-mail: <a href="mailto:uarep@jerele.eu">uarep@jerele.eu</a> тел. +38 (044) 360 30 11</p>  <p>UA.TR.120</p>

#### EQUIPMENT SYMBOLS



Manufacturer



Consult instructions for use



European Authorized Representative



Medical Device

APN 099-40119, Rev D