








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
<p>US</p>  <p>Apple Inc. One Apple Park Way Cupertino, CA 95014 www.apple.com Apple Distribution International Hollyhill Industrial Estate, Hollyhill, Cork, Ireland Contact: medicalcompliance@group.apple.com</p>					
<p>EU</p> <div style="border: 1px solid black; padding: 2px; display: inline-block; margin-bottom: 5px;">EC REP</div> <p>Apple Distribution International Hollyhill Industrial Estate, Hollyhill, Cork, Ireland</p> <p>Contact: medicalcompliance@group.apple.com</p> 	<div style="border: 1px solid black; padding: 2px; display: inline-block; margin-bottom: 5px;">EC REP</div> <p>Apple Distribution International Hollyhill Industrial Estate, Hollyhill, Cork, Ireland</p> <p>Contact: medicalcompliance@group.apple.com</p>  <div style="border: 1px solid black; padding: 5px; display: inline-block; margin-top: 10px;">MD</div>	<div style="border: 1px solid black; padding: 2px; display: inline-block; margin-bottom: 5px;">EC REP</div> <p>Apple Distribution International Hollyhill Industrial Estate, Hollyhill, Cork, Ireland</p> <p>Contact: medicalcompliance@group.apple.com</p> 	<div style="border: 1px solid black; padding: 2px; display: inline-block; margin-bottom: 5px;">EC REP</div> <p>Apple Distribution International Hollyhill Industrial Estate, Hollyhill, Cork, Ireland</p> <p>Contact: medicalcompliance@group.apple.com</p>  <div style="border: 1px solid black; padding: 5px; display: inline-block; margin-top: 10px;">MD</div>	<div style="border: 1px solid black; padding: 2px; display: inline-block; margin-bottom: 5px;">EC REP</div> <p>Apple Distribution International Hollyhill Industrial Estate, Hollyhill, Cork, Ireland</p> <p>Contact: medicalcompliance@group.apple.com</p>  <div style="border: 1px solid black; padding: 5px; display: inline-block; margin-top: 10px;">MD</div>	<div style="border: 1px solid black; padding: 2px; display: inline-block; margin-bottom: 5px;">EC REP</div> <p>Apple Distribution International Hollyhill Industrial Estate, Hollyhill, Cork, Ireland</p> <p>Contact: medicalcompliance@group.apple.com</p>  <div style="border: 1px solid black; padding: 5px; display: inline-block; margin-top: 10px;">MD</div>


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AUSTRALIA AND TERRITORIES (CHRISTMAS ISLAND, COCOS (KEELING) ISLANDS, HEARD AND MCDONALD ISLANDS, NORFOLK ISLAND)	Not Available	Sponsor Details: Apple Pty Ltd Level 3, 20 Martin Place Sydney NSW 2000 Australia https://www.apple.com/au/ TEL: 1-300-321-456			
BRAZIL	ANVISA Nº: 80117580880 RESPONSÁVEL TÉCNICO: LUIZ LEVY CRUZ MARTINS – CRF-SP: 42415 DETENTOR DA NOTIFICAÇÃO: 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: brazilvigilance@ul.com	ANVISA Nº: 80117580880 RESPONSÁVEL TÉCNICO: LUIZ LEVY CRUZ MARTINS – CRF-SP: 42415 DETENTOR DA NOTIFICAÇÃO: 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: brazilvigilance@ul.com	ANVISA Nº: 80117580881 RESPONSÁVEL TÉCNICO: LUIZ LEVY CRUZ MARTINS – CRF-SP: 42415 DETENTOR DA NOTIFICAÇÃO: 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: brazilvigilance@ul.com	ANVISA Nº: 80117580881 RESPONSÁVEL TÉCNICO: LUIZ LEVY CRUZ MARTINS – CRF-SP: 42415 DETENTOR DA NOTIFICAÇÃO: 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: brazilvigilance@ul.com	ANVISA Nº: 80117581018 RESPONSÁVEL TÉCNICO: LUIZ LEVY CRUZ MARTINS – CRF-SP: 42415 DETENTOR DA NOTIFICAÇÃO: 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: brazilvigilance@ul.com

Feature version/ Regulatory Registration Information	ECG V1	ECG V2	IRNF V1	IRNF V2	Afib History
COLOMBIA	<p>PRODUCTO: Software de Electrografía y aplicación de ECG para software de análisis de fotopleitismografía</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 fotopleitismografía</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>
INDIA	<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>
INDONESIA	<p>Not Available</p>	<p>Product License Number: KEMENKES RI AKL 20502121822</p> <p>REGISTRANT:</p> <p>PT. ASIA ACTUAL INDONESIA, DKI Jakarta Gandaria 8 Office Tower, Unit 6J. Jl. Sultan Iskandar Muda Jakarta Selatan 12240 – Indonesia +62 (021) 2930-3747</p>	<p>Product License Number: KEMENKES RI AKL 20502121725</p> <p>REGISTRANT:</p> <p>PT. ASIA ACTUAL INDONESIA, DKI Jakarta Gandaria 8 Office Tower, Unit 6J. Jl. Sultan Iskandar Muda Jakarta Selatan 12240 – Indonesia +62 (021) 2930-3747</p>	<p>Product License Number: KEMENKES RI AKL 20502220301</p> <p>REGISTRANT:</p> <p>PT. ASIA ACTUAL INDONESIA, DKI Jakarta Gandaria 8 Office Tower, Unit 6J. Jl. Sultan Iskandar Muda Jakarta Selatan 12240 – Indonesia +62 (021) 2930-3747</p>	<p>Product License Number: KEMENKES RI AKL 20502220325</p> <p>REGISTRANT:</p> <p>PT. ASIA ACTUAL INDONESIA, DKI Jakarta Gandaria 8 Office Tower, Unit 6J. Jl. Sultan Iskandar Muda Jakarta Selatan 12240 – Indonesia +62 (021) 2930-3747</p>




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ISRAEL AMAR REGISTRATION HOLDER	<p>AMAR REGISTRATION HOLDER:</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>מדוגר מכשור רפואי בע"מ הסדנא 8 ת.ד. 2566 רעננה 4365104 טל: 09-7401457 פקס: 09-7401459</p> <p>מידוגאר للأجهزة الطبية المحدودة شارع هاسادنا 8, ص.ب. 2566 رعناتا 4365104</p> <p>www.medogar.co.il info@medogar.co.il</p> <p>AMAR Certificate Number: 21080016</p>	<p>AMAR REGISTRATION HOLDER:</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>מדוגר מכשור רפואי בע"מ הסדנא 8 ת.ד. 2566 רעננה 4365104 טל: 09-7401457 פקס: 09-7401459</p> <p>מידוגאר للأجهزة الطبية المحدودة شارع هاسادنا 8, ص.ب. 2566 رعناتا 4365104</p> <p>www.medogar.co.il info@medogar.co.il</p> <p>AMAR Certificate Number: 21080016</p>	<p>AMAR REGISTRATION HOLDER:</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>מדוגר מכשור רפואי בע"מ הסדנא 8 ת.ד. 2566 רעננה 4365104 טל: 09-7401457 פקס: 09-7401459</p> <p>מידוגאר للأجهزة الطبية المحدودة شارع هاسادنا 8, ص.ب. 2566 رعناتا 4365104</p> <p>www.medogar.co.il info@medogar.co.il</p> <p>AMAR Certificate Number: 21080017</p>	<p>AMAR REGISTRATION HOLDER:</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>מדוגר מכשור רפואי בע"מ הסדנא 8 ת.ד. 2566 רעננה 4365104 טל: 09-7401457 פקס: 09-7401459</p> <p>מידוגאר للأجهزة الطبية المحدودة شارع هاسادنا 8, ص.ب. 2566 رعناتا 4365104</p> <p>www.medogar.co.il info@medogar.co.il</p> <p>AMAR Certificate Number: 21080018</p>	<p>AMAR REGISTRATION HOLDER:</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>מדוגר מכשור רפואי בע"מ הסדנא 8 ת.ד. 2566 רעננה 4365104 טל: 09-7401457 פקס: 09-7401459</p> <p>מידוגאר للأجهزة الطبية المحدودة شارع هاسادنا 8, ص.ب. 2566 رعناتا 4365104</p> <p>www.medogar.co.il info@medogar.co.il</p> <p>AMAR Certificate Number: 21080020</p>
MALAYSIA	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: kenna@nyprax.com 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: kenna@nyprax.com 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: kenna@nyprax.com 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: kenna@nyprax.com Tel: +6012 620 1824</p>


Feature version/ Regulatory Registration Information	ECG V1	ECG V2	IRNF V1	IRNF V2	Afib History
MEXICO	Not Available	AUTHORIZED REPRESENTATIVE: Emergo S. de R.L. de C.V. Avenida Álvaro Obregón No. 273-403, Colonia Roma, C.P. 06700, Cuauhtémoc, Ciudad de México, México.	Not Available	AUTHORIZED REPRESENTATIVE: Emergo S. de R.L. de C.V. Avenida Álvaro Obregón No. 273-403, Colonia Roma, C.P. 06700, Cuauhtémoc, Ciudad de México, México.	Registration Number: 1493W2024 SSA AUTHORIZED REPRESENTATIVE: Emergo S. de R.L. de C.V. Avenida Álvaro Obregón No. 273-403, Colonia Roma, C.P. 06700, Cuauhtémoc, Ciudad de México, México.
MOLDOVA	Not Available	Registration Number: DM000322299, DM000322300 AUTHORIZED REPRESENTATIVE: JERELO S.R.L. MD-2024, str. Pietrăriei, nr 19A, of. 3. mun. Chişinău, Republica Moldova +37378538295	Registration Number: DM000322301, DM000322302 AUTHORIZED REPRESENTATIVE: JERELO S.R.L. MD-2024, str. Pietrăriei, nr 19A, of. 3. mun. Chişinău, Republica Moldova +37378538295	Registration Number: DM000322301, DM000322302 AUTHORIZED REPRESENTATIVE: JERELO S.R.L. MD-2024, str. Pietrăriei, nr 19A, of. 3. mun. Chişinău, Republica Moldova +37378538295	Registration Number: DM000322299, DM000322300 AUTHORIZED REPRESENTATIVE: JERELO S.R.L. MD-2024, str. Pietrăriei, nr 19A, of. 3. mun. Chişinău, Republica Moldova +37378538295
PERU	Registro Sanitario N° :DB5982E IMPORTADOR: Drogería Emergo Peru S.R.L. Calle Las Orquídeas Nro. 585, Int. 1301, San Isidro, Lima, Perú RUC: 205 52 75 65 34	Registro Sanitario N° :DB5982E IMPORTADOR: Drogería Emergo Peru S.R.L. Calle Las Orquídeas Nro. 585, Int. 1301, San Isidro, Lima, Perú RUC: 205 52 75 65 34	Registro Sanitario N° :DB6240E IMPORTADOR: Drogería Emergo Peru S.R.L. Calle Las Orquídeas Nro. 585, Int. 1301, San Isidro, Lima, Perú RUC: 205 52 75 65 34	Registro Sanitario N° :DB6240E IMPORTADOR: Drogería Emergo Peru S.R.L. Calle Las Orquídeas Nro. 585, Int. 1301, San Isidro, Lima, Perú RUC: 205 52 75 65 34	Registro Sanitario N° :DB7939E IMPORTADOR: Drogería Emergo Peru S.R.L. Calle Las Orquídeas Nro. 585, Int. 1301, San Isidro, Lima, Perú RUC: 205 52 75 65 34

Feature version/ Regulatory Registration Information	ECG V1	ECG V2	IRNF V1	IRNF V2	Afib History
<p>REPUBLIC OF KOREA</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>
<p>SWITZERLAND</p>	<p>CH-REP:</p> <p>QUNIQUE GmbH Bahnhofweg 17 5610 Wohlen Switzerland</p>				

Feature version/ Regulatory Registration Information	ECG V1	ECG V2	IRNF V1	IRNF V2	Afib History
THAILAND	<p>Medical Device License Number: 64-2-2-2-0004085</p> <p>IMPORTER:</p> <p>บริษัท เอเซีย แอคซเวล (ประเทศไทย) จำกัด 8 อาคารทีวีวัน ห้องเลขที่ 15-102 ชั้น 15 ซอยสุขุมวิท 40 ถนนสุขุมวิท แขวงพระโขนง เขตคลองเตย กรุงเทพฯ 10110 โทร. 02-821-5998</p>	<p>Medical Device License Number: 64-2-2-2-0004085</p> <p>IMPORTER:</p> <p>บริษัท เอเซีย แอคซเวล (ประเทศไทย) จำกัด 8 อาคารทีวีวัน ห้องเลขที่ 15-102 ชั้น 15 ซอยสุขุมวิท 40 ถนนสุขุมวิท แขวงพระโขนง เขตคลองเตย กรุงเทพฯ 10110 โทร. 02-821-5998</p>	<p>Medical Device License Number: 64-2-2-2-0002928</p> <p>IMPORTER:</p> <p>บริษัท เอเซีย แอคซเวล (ประเทศไทย) จำกัด 8 อาคารทีวีวัน ห้องเลขที่ 15-102 ชั้น 15 ซอยสุขุมวิท 40 ถนนสุขุมวิท แขวงพระโขนง เขตคลองเตย กรุงเทพฯ 10110 โทร. 02-821-5998</p>	<p>Medical Device License Number: 65-2-2-2-0016259</p> <p>IMPORTER:</p> <p>บริษัท เอเซีย แอคซเวล (ประเทศไทย) จำกัด 8 อาคารทีวีวัน ห้องเลขที่ 15-102 ชั้น 15 ซอยสุขุมวิท 40 ถนนสุขุมวิท แขวงพระโขนง เขตคลองเตย กรุงเทพฯ 10110 โทร. 02-821-5998</p>	<p>Medical Device License Number: 65-2-2-2-0015185</p> <p>IMPORTER:</p> <p>บริษัท เอเซีย แอคซเวล (ประเทศไทย) จำกัด 8 อาคารทีวีวัน ห้องเลขที่ 15-102 ชั้น 15 ซอยสุขุมวิท 40 ถนนสุขุมวิท แขวงพระโขนง เขตคลองเตย กรุงเทพฯ 10110 โทร. 02-821-5998</p>
TURKEY	<p>Apple Teknoloji ve Satış Limited Şirketi Buyükdere Caddesi Levent 199 Kat:22-23 34394 Şişli İstanbul Türkiye</p>				
UKRAINE	<p>ТОВ «ДЖЕРЕЛО-УКРАЇНА» 01033, Україна, м. Київ, вулиця Шота Руставелі 33-Б, офіс 27 e-mail: uarep@jerele.eu тел. +38 (044) 360 30 11</p>  <p>UA.TR.120</p>				
VIETNAM	<p>Product License Number: 220002518/PCBB-HCM</p> <p>REGISTRANT:</p> <p>Asia Actual Vietnam Co., LTD. 45/90 Binh Tien, Ward 7, District 6, Ho Chi Minh City, Vietnam</p> <p>+84 969159420</p>	<p>Product License Number: 220002519/PCBB-HCM</p> <p>REGISTRANT:</p> <p>Asia Actual Vietnam Co., LTD. 45/90 Binh Tien, Ward 7, District 6, Ho Chi Minh City, Vietnam</p> <p>+84 969159420</p>	<p>Product License Number: 220002520/PCBB-HCM</p> <p>REGISTRANT:</p> <p>Asia Actual Vietnam Co., LTD. 45/90 Binh Tien, Ward 7, District 6, Ho Chi Minh City, Vietnam</p> <p>+84 969159420</p>	<p>Product License Number: 220002521/PCBB-HCM</p> <p>REGISTRANT:</p> <p>Asia Actual Vietnam Co., LTD. 45/90 Binh Tien, Ward 7, District 6, Ho Chi Minh City, Vietnam</p> <p>+84 969159420</p>	<p>Product License Number: 220003108/PCBB-HCM</p> <p>REGISTRANT:</p> <p>Asia Actual Vietnam Co., LTD. 45/90 Binh Tien, Ward 7, District 6, Ho Chi Minh City, Vietnam</p> <p>+84 969159420</p>

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

Feature version/ Regulatory Registration Information	CT
US	 <p>Apple Inc. One Apple Park Way Cupertino, CA 95014 www.apple.com Apple Distribution International Hollyhill Industrial Estate, Hollyhill, Cork, Ireland Contact: medicalcompliance@group.apple.com</p>
EU	 <p>Apple Distribution International Hollyhill Industrial Estate, Hollyhill, Cork, Ireland Contact: medicalcompliance@group.apple.com</p> 
ISRAEL	<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>מדוגר מכשור רפואי בע"מ הסדנא 8 ת.ד. 2566 רעננה 4365104 טל: 09-7401457 פקס: 09-7401459</p> <p>میدوگار للأجهزة الطبية المحدودة شارع هاسادنا 8، ص.ب. 2566 رعنانا 4365104</p> <p>www.medogar.co.il info@medogar.co.il</p> <p>AMAR Certificate Number: 21080019</p>

Feature version/ Regulatory Registration Information	CT
MOLDOVA	<p>AUTHORIZED REPRESENTATIVE:</p> <p>JERELO S.R.L. MD-2024, str. Pietrăriei, nr 19A, of. 3. mun. Chişinău, Republica Moldova +37378538295</p>
SWITZERLAND	<p>CH-REP:</p> <p>QUNIQUE GmbH Bahnhofweg 17 5610 Wohlen Switzerland</p>
UKRAINE	<p>ТОВ «ДЖЕРЕЛО-УКРАЇНА» 01033, Україна, м. Київ, вулиця Шота Руставелі 33-Б, офіс 27 e-mail: uarep@jerele.eu тел. +38 (044) 360 30 11</p> <div data-bbox="646 834 753 941" style="text-align: center;">  </div> <p>UA.TR.120</p>

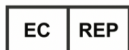
EQUIPMENT SYMBOLS



Manufacturer



Consult instructions for use



European Authorized Representative



APN 099-40119, Rev E