

## Health Features 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. Health Applications
- B. Cycle Tracking App

Table A - Health Applications Regulatory Registration Information

| Feature | ECG App 1.X                                                                                                                                                                                                                                                                                                                                                                                                                                   | ECG App 2.X | Irregular Rhythm Notification Feature (1.X) | Irregular Rhythm Notification Feature (2.X) | Atrial Fibrillation History Feature | Sleep Apnea Notification Feature | Hearing Aid Feature (1.X) | Hearing Test Feature | Hypertension Notification Feature | Hearing Aid Feature (2.X) | Digital Prism Correction Feature |
|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|---------------------------------------------|---------------------------------------------|-------------------------------------|----------------------------------|---------------------------|----------------------|-----------------------------------|---------------------------|----------------------------------|
| US      | <br>Apple Inc.<br>One Apple Park Way Cupertino, CA 95014<br><br><a href="http://www.apple.com">www.apple.com</a><br><b>Contact:</b> <a href="mailto:medicalcompliance@group.apple.com">medicalcompliance@group.apple.com</a>                                                                                                                                 |             |                                             |                                             |                                     |                                  |                           |                      |                                   |                           |                                  |
| EU      | <div> <div>EU</div> <div>REP</div> </div> Apple Distribution International<br>Hollyhill Industrial Estate,<br>Hollyhill, Cork,<br>Ireland<br><br>Contact: <a href="mailto:medicalcompliance@group.apple.com">medicalcompliance@group.apple.com</a><br><br> 0123<br><br> |             |                                             |                                             |                                     |                                  |                           |                      |                                   | Not Available             |                                  |

| Feature   | ECG App 1.X                                                                                                                                                                                                                                                                                                                                                                                                                                              | ECG App 2.X                                                                                                                                                                                                                                     | Irregular Rhythm Notification Feature (1.X) | Irregular Rhythm Notification Feature (2.X) | Atrial Fibrillation History Feature | Sleep Apnea Notification Feature | Hearing Aid Feature (1.X) | Hearing Test Feature   | Hypertension Notification Feature | Hearing Aid Feature (2.X) | Digital Prism Correction Feature |
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| AUSTRALIA | Not Available                                                                                                                                                                                                                                                                                                                                                                                                                                            | <div><div>AU</div><div>REP</div></div> <p>Sponsor Details:</p> <p>Apple Pty Ltd<br/>Level 3, 20 Martin Place<br/>Sydney NSW 2000<br/>Australia<br/><a href="https://www.apple.com/au/">https://www.apple.com/au/</a><br/>TEL: 1-300-321-456</p> |                                             |                                             |                                     |                                  |                           |                        |                                   | Not Available             |                                  |
| BRAZIL    | ANVISA Nº: 80117580880                                                                                                                                                                                                                                                                                                                                                                                                                                   | ANVISA Nº: 80117580880                                                                                                                                                                                                                          | ANVISA Nº: 80117580881                      | ANVISA Nº: 80117580881                      | ANVISA Nº: 80117581018              | ANVISA Nº: 80117581190           | ANVISA Nº: 80117581206    | ANVISA Nº: 80117581198 | Not Available                     |                           |                                  |
|           | <div><div>BR</div><div>REP</div></div> <p>RESPONSÁVEL TÉCNICO:<br/>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.<br/>Avenida Francisco Matarazzo, 1.752, Salas 502/503, Água Branca, São Paulo-SP, CEP – 05001-200<br/>CNPJ: 04.967.408/0001-98<br/>E-mail: <a href="mailto:brazilvigilance@ul.com">brazilvigilance@ul.com</a></p> |                                                                                                                                                                                                                                                 |                                             |                                             |                                     |                                  |                           |                        |                                   |                           |                                  |

| Feature  | ECG App 1.X                                                                                                                                                                           | ECG App 2.X | Irregular Rhythm Notification Feature (1.X)                                          | Irregular Rhythm Notification Feature (2.X)                        | Atrial Fibrillation History Feature                     | Sleep Apnea Notification Feature | Hearing Aid Feature (1.X)                                                                                                                                                               | Hearing Test Feature                                                                  | Hypertension Notification Feature | Hearing Aid Feature (2.X) | Digital Prism Correction Feature |
|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|--------------------------------------------------------------------------------------|--------------------------------------------------------------------|---------------------------------------------------------|----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|-----------------------------------|---------------------------|----------------------------------|
| COLOMBIA | REGISTRO SANITARIO NO.: INVIMA 2020DM-0021828                                                                                                                                         |             | REGISTRO SANITARIO NO.: INVIMA 2020DM-0021835                                        |                                                                    | REGISTRO SANITARIO NO.: INVIMA 2022DM-0026135           | Not Available                    | REGISTRO SANITARIO NO.: INVIMA 2025DM-0030019                                                                                                                                           | REGISTRO SANITARIO NO.: INVIMA 2024DM-0029973                                         | Not Available                     |                           |                                  |
|          | PRODUCTO: Software de Electrografía y aplicación de ECG para software de análisis de fotopletismografía                                                                               |             | PRODUCTO: Función de notificación de ritmo irregular (IRNF por sus siglas en ingles) | PRODUCTO: Función de notificación de ritmo irregular (Version 2.X) | PRODUCTO: Funcion de Historial de Fibrilación Auricular |                                  | PRODUCTO: FUNCION DE ASISTENCIA AUDITIVA (VERSION 1.X) -FUNCION DE ASISTENCIA AUDITIVA                                                                                                  | PRODUCTO: FUNCIÓN DE PRUEBA DE AUDICIÓN (VERSIÓN 1.X) - FUNCIÓN DE PRUEBA DE AUDICIÓN | Not Available                     |                           |                                  |
|          | <br><br>IMPORTADOR:<br><br>IMPOMED S.A.S<br>Calle 1 SUR NO. 77A-21<br>Interior 201 Medellin Colombia |             |                                                                                      |                                                                    |                                                         |                                  | <br><br>IMPORTADOR:<br><br>IMPOMED S.A.S<br>Calle 1 SUR NO. 77A-21<br>Interior 201 Medellín Colombia |                                                                                       |                                   |                           |                                  |



| Feature   | ECG App 1.X                                                                                                                                                                 | ECG App 2.X                                                                                                                                                      | Irregular Rhythm Notification Feature (1.X)          | Irregular Rhythm Notification Feature (2.X)          | Atrial Fibrillation History Feature                  | Sleep Apnea Notification Feature                    | Hearing Aid Feature (1.X)                           | Hearing Test Feature                                | Hypertension Notification Feature | Hearing Aid Feature (2.X) | Digital Prism Correction Feature |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|------------------------------------------------------|------------------------------------------------------|-----------------------------------------------------|-----------------------------------------------------|-----------------------------------------------------|-----------------------------------|---------------------------|----------------------------------|
| INDIA     | Import License Number: IMP/MD/2022/000754<br><br>IMPORTER:<br><br>Asia Actual India (OPC) Pvt. Ltd.<br>523A, Tower A, Spaze I-Tech Park, Sector 49, Gurgaon, Haryana, India |                                                                                                                                                                  |                                                      |                                                      |                                                      | Not Available                                       |                                                     |                                                     |                                   |                           |                                  |
| INDONESIA | Not Available                                                                                                                                                               | Product License Number: KEMENKES RI AKL 2050212182 2                                                                                                             | Product License Number: KEMENKES RI AKL 2050212172 5 | Product License Number: KEMENKES RI AKL 2050222030 1 | Product License Number: KEMENKES RI AKL 2050222032 5 | Product License Number: KEMENKES RI AKL 20402520019 | Product License Number: KEMENKES RI AKL 20702520043 | Product License Number: KEMENKES RI AKL 20701520007 | Not Available                     |                           |                                  |
|           |                                                                                                                                                                             | PT. ASIA ACTUAL INDONESIA, DKI Jakarta<br>Gandaria 8 Office Tower, Unit 6J. Jl. Sultan Iskandar Muda<br>Jakarta Selatan 12240 – Indonesia<br>+62 (021) 2930-3747 |                                                      |                                                      |                                                      |                                                     |                                                     |                                                     |                                   |                           |                                  |

| Feature | ECG App 1.X                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | ECG App 2.X                       | Irregular Rhythm Notification Feature (1.X) | Irregular Rhythm Notification Feature (2.X) | Atrial Fibrillation History Feature | Sleep Apnea Notification Feature  | Hearing Aid Feature (1.X)         | Hearing Test Feature              | Hypertension Notification Feature | Hearing Aid Feature (2.X) | Digital Prism Correction Feature |
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| ISRAEL  | AMAR Certificate Number: 21080016                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | AMAR Certificate Number: 21080016 | AMAR Certificate Number: 21080017           | AMAR Certificate Number: 21080018           | AMAR Certificate Number: 21080020   | AMAR Certificate Number: 21080022 | AMAR Certificate Number: 21080023 | AMAR Certificate Number: 21080024 | Not Available                     |                           |                                  |
|         | <div><div>IL</div><div>REP</div></div> <div>AMAR REGISTRATION HOLDER:</div> <div>Medogar Medical Equipment Ltd.<br/>Hasadna St. 8 P.O.B 2586 Ra'annana 4365104 ISRAEL<br/>Office Tel: +972-9-7401457<br/>Fax: +972-9-7401459</div> <div>מדוגר מכשור רפואי בע"מ<br/>הסדנא 8 ת.ד. 2566 רעננה 4365104<br/>טל: 09-7401457<br/>פקס: 09-7401459</div> <div>ميدوغار للأجهزة الطبية المحدودة<br/>شارع هاسادنا 8، ص.ب. 2566<br/>رعناتا 4365104</div> <div><a href="http://www.medogar.co.il">www.medogar.co.il</a> <a href="mailto:info@medogar.co.il">info@medogar.co.il</a></div> |                                   |                                             |                                             |                                     |                                   |                                   |                                   |                                   |                           |                                  |

| Feature  | ECG App 1.X   | ECG App 2.X                                                                                                                                                                                                                                                                                                                                            | Irregular Rhythm Notification Feature (1.X)  | Irregular Rhythm Notification Feature (2.X)                                                                                                                                                                    | Atrial Fibrillation History Feature           | Sleep Apnea Notification Feature              | Hearing Aid Feature (1.X)                     | Hearing Test Feature                          | Hypertension Notification Feature | Hearing Aid Feature (2.X) | Digital Prism Correction Feature |
|----------|---------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|-----------------------------------------------|-----------------------------------------------|-----------------------------------------------|-----------------------------------|---------------------------|----------------------------------|
| MALAYSIA | Not Available | Product License/MDA Reg No.: GB7992021-54025                                                                                                                                                                                                                                                                                                           | Product License/MDA Reg No.: GB7830421-55921 |                                                                                                                                                                                                                | Product License/MDA Reg No.: GB5330222-102051 | Product License/MDA Reg No.: GB6685125-193304 | Product License/MDA Reg No.: GB5836625-195095 | Product License/MDA Reg No.: GB3808525-195099 | Not Available                     |                           |                                  |
|          |               | <div><div>MY</div><div>REP</div></div> <p>AUTHORIZED REPRESENTATIVE:</p> <p>Nyprax Business Solutions<br/>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><br/>Tel: +6012 620 1824</p> |                                              |                                                                                                                                                                                                                |                                               |                                               |                                               |                                               |                                   |                           |                                  |
| MEXICO   | Not Available | Registration Number: 0155W2025 SSA                                                                                                                                                                                                                                                                                                                     | Not Available                                | Registration Number: 3198W2024 SSA                                                                                                                                                                             | Registration Number: 1493W2024 SSA            | Not Available                                 |                                               |                                               |                                   |                           |                                  |
|          |               | <div><div>MX</div><div>REP</div></div> <p>AUTHORIZED REPRESENTATIVE:<br/>Emergo S. de R.L. de C.V.<br/>Avenida Álvaro Obregón No. 273-403, Colonia Roma, C.P. 06700, Cuauhtémoc, Ciudad de México, México.</p>                                                                                                                                         |                                              | <div><div>MX</div><div>REP</div></div> <p>AUTHORIZED REPRESENTATIVE:<br/>Emergo S. de R.L. de C.V.<br/>Avenida Álvaro Obregón No. 273-403, Colonia Roma, C.P. 06700, Cuauhtémoc, Ciudad de México, México.</p> |                                               |                                               |                                               |                                               |                                   |                           |                                  |



| Feature           | ECG App 1.X                                                                                                                                                                                                                     | ECG App 2.X | Irregular Rhythm Notification Feature (1.X) | Irregular Rhythm Notification Feature (2.X) | Atrial Fibrillation History Feature | Sleep Apnea Notification Feature | Hearing Aid Feature (1.X) | Hearing Test Feature | Hypertension Notification Feature | Hearing Aid Feature (2.X) | Digital Prism Correction Feature |
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| REPUBLIC OF KOREA | <p>본 앱은 “의료기기” 임.</p> <p>수입업자: 이머고코리아 (유)<br/>06236) 서울특별시 강남구 테헤란로 152 강남파이낸스센터 26층<br/>제조원: Apple Inc.<br/>(본사) One Apple Park Way, Cupertino, CA 95014, USA<br/>(공장) 20450 Stevens Creek Blvd., Cupertino, CA 95014, USA</p> |             |                                             |                                             |                                     |                                  |                           |                      | Not Available                     |                           |                                  |

| Feature           | ECG App 1.X                                                                                                                                                                                                                                                                           | ECG App 2.X                                                                                                                                                                                                                                                                           | Irregular Rhythm Notification Feature (1.X)                                                                                                                                                                                                                                                     | Irregular Rhythm Notification Feature (2.X)                                                                                                                                                                                                                                                     | Atrial Fibrillation History Feature                                                                                                                                                                                                                                                                                                                       | Sleep Apnea Notification Feature                                                                                                                                                                                                                                                                                                       | Hearing Aid Feature (1.X)                                                                                                                                                                                                                     | Hearing Test Feature                                                                                                                                                                                 | Hypertension Notification Feature | Hearing Aid Feature (2.X) | Digital Prism Correction Feature |
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| REPUBLIC OF KOREA | <p>허가번호: 수허 20-177 호</p> <p>명칭 (제품명, 품목명, 모델명): 심전도 앱, 심전계, ECG App 소프트웨어 버전: 1.X<br/>출시연월: 2020년 11월<br/>포장단위: 1ea</p> <p>사용목적: 모바일플랫폼 (Apple Watch)에 장착된 심전도 (ECG)센서를 이용하여 측정된 단일유도 (Lead I) 유사 심전도 신호로부터 심방세동 또는 정상박동 존재 여부를 판정함으로써, 심전도 신호를 생성, 기록, 저장, 전송 및 표시하는 의료용 어플리케이션.</p> | <p>허가번호: 수허 20-177 호</p> <p>명칭 (제품명, 품목명, 모델명): 심전도 앱, 심전계, ECG App 소프트웨어 버전: 2.X<br/>출시연월: 2022년 01월<br/>포장단위: 1ea</p> <p>사용목적: 모바일플랫폼 (Apple Watch)에 장착된 심전도 (ECG)센서를 이용하여 측정된 단일유도 (Lead I) 유사 심전도 신호로부터 심방세동 또는 정상박동 존재 여부를 판정함으로써, 심전도 신호를 생성, 기록, 저장, 전송 및 표시하는 의료용 어플리케이션.</p> | <p>허가번호: 수허 20-176 호</p> <p>명칭 (제품명, 품목명, 모델명): 불규칙한 박동 알림 기능, 휴대형심전도분석소프트웨어, Irregular Rhythm Notification Feature (IRNF)<br/>출시연월: 2020년 11월<br/>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>허가번호: 수허 20-176 호</p> <p>명칭 (제품명, 품목명, 모델명): 불규칙한 박동 알림 기능, 휴대형심전도분석소프트웨어, Irregular Rhythm Notification Feature (IRNF)<br/>출시연월: 2020년 11월<br/>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>허가번호: 수허 23-138 호</p> <p>명칭 (제품명, 품목명, 모델명): 휴대형심전도분석소프트웨어, AFHF, Atrial Fibrillation History Feature (AFHF)<br/>출시연월: 2023년 7월<br/>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>허가번호: 수허 25-128 호</p> <p>명칭 (제품명, 품목명, 모델명): 이머고코리아(유)·Sleep Apnea Notification Feature (SANF), 휴대형 호흡 분석 소프트웨어, Sleep Apnea Notification Feature (SANF)<br/>출시연월: 2025년 9월<br/>포장단위: 1ea</p> <p>사용목적: 수면 중 모바일플랫폼(스마트워치)의 가속도계 (accelerometer (Accel)) 센서 데이터를 분석하여, 중등도에서 중증 수면 무호흡증과 관련된 호흡 장애 패턴을 식별하고 사용자에게 알림을 제공하는 소프트웨어</p> | <p>허가번호: 수허 25-100 호</p> <p>이머고코리아(유)·Hearing Aid Feature (HAF), 이비인후과학 진료용 소프트웨어, Hearing Aid Feature (HAF)<br/>출시연월: 2025년 9월<br/>포장단위: 1ea</p> <p>사용목적: 호환되는 웨어러블 전자 기기를 통해 청력(mild)에서 중도 (moderate)의 청각 장애가 있는 사람에게 소리를 증폭시켜 주는 소프트웨어</p> | <p>허가번호: 수허 25-99 호</p> <p>이머고코리아(유)·Hearing Test Feature (HTF), 청력 검사 소프트웨어, Hearing Test Feature (HTF)<br/>출시연월: 2025년 9월<br/>포장단위: 1ea</p> <p>사용목적: 웨어러블 전자 기기를 통해 청력을 검사하여 청력도를 볼 수 있는 소프트웨어</p> | Not Available                     |                           |                                  |

| Feature     | ECG App 1.X                                                                                                                                                                                | ECG App 2.X | Irregular Rhythm Notification Feature (1.X)     | Irregular Rhythm Notification Feature (2.X)     | Atrial Fibrillation History Feature             | Sleep Apnea Notification Feature                | Hearing Aid Feature (1.X)                       | Hearing Test Feature                            | Hypertension Notification Feature | Hearing Aid Feature (2.X) | Digital Prism Correction Feature |
|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|-----------------------------------|---------------------------|----------------------------------|
| SERBIA      | <div><div>RS</div><div>REP</div></div> <p>AUTHORIZED REPRESENTATIVE:</p> <p>KK Pharma<br/>Leader d.o.o.,<br/>Tiršova 5a, 11000<br/>Belgrade, Republic<br/>of Serbia</p>                    |             |                                                 |                                                 |                                                 |                                                 |                                                 |                                                 |                                   | Not Available             |                                  |
|             |                                                                                                                                                                                            |             |                                                 |                                                 |                                                 |                                                 |                                                 |                                                 |                                   |                           |                                  |
| SWITZERLAND | <div><div>CH</div><div>REP</div></div> <p><b>CH-REP:</b></p> <p>QUNIQUE GmbH<br/>Bahnhofweg 17<br/>5610 Wohlen<br/>Switzerland</p>                                                         |             |                                                 |                                                 |                                                 |                                                 |                                                 |                                                 |                                   | Not Available             |                                  |
|             |                                                                                                                                                                                            |             |                                                 |                                                 |                                                 |                                                 |                                                 |                                                 |                                   |                           |                                  |
| THAILAND    | Medical Device License Number: 64-2-2-2-0004085                                                                                                                                            |             | Medical Device License Number: 64-2-2-2-0002928 | Medical Device License Number: 65-2-2-2-0016259 | Medical Device License Number: 65-2-2-2-0015185 | Medical Device License Number: 68-2-2-2-0001249 | Medical Device License Number: 68-2-2-2-0000931 | Medical Device License Number: 68-2-2-2-0002661 | Not Available                     |                           |                                  |
|             | IMPORTER:<br><br>บริษัท เอเชีย แคคชาล (ประเทศไทย) จำกัด<br>8 อาคารที่วัน ห้องเลขที่ 15-102 ชั้น 15 ซอยสุขุมวิท 40 ถนนสุขุมวิท<br>แขวงพระโขนง เขตคลองเตย กรุงเทพฯ 10110<br>โทร. 02-821-5998 |             |                                                 |                                                 |                                                 |                                                 |                                                 |                                                 |                                   |                           |                                  |
| TURKEY      | Apple Teknoloji ve Satış Limited Şirketi<br>Büyükdere Caddesi<br>Levent 199 Kat:22-23<br>34394 Şişli<br>İstanbul<br>Türkiye                                                                |             |                                                 |                                                 |                                                 |                                                 | Not Available                                   |                                                 |                                   |                           |                                  |

| Feature | ECG App 1.X                                                                                                                             | ECG App 2.X                                                                                                                                                                                                                                                                                                                                      | Irregular Rhythm Notification Feature (1.X) | Irregular Rhythm Notification Feature (2.X) | Atrial Fibrillation History Feature        | Sleep Apnea Notification Feature           | Hearing Aid Feature (1.X)                  | Hearing Test Feature                       | Hypertension Notification Feature | Hearing Aid Feature (2.X) | Digital Prism Correction Feature |
|---------|-----------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|---------------------------------------------|--------------------------------------------|--------------------------------------------|--------------------------------------------|--------------------------------------------|-----------------------------------|---------------------------|----------------------------------|
| UKRAINE | Not Available                                                                                                                           | <div><div>UA</div><div>REP</div></div> <p>ТОВ «ДЖЕРЕЛО-УКРАЇНА»<br/>01033, Україна, м. Київ, вулиця Шота Руставелі 33-Б, офіс 27<br/>e-mail: <a href="mailto:uarep@jerelo.eu">uarep@jerelo.eu</a><br/>тел. +38 (044) 360 30 11</p> <div></div> <p>UA.TR.120</p> |                                             |                                             |                                            |                                            |                                            |                                            | Not Available                     |                           |                                  |
|         |                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                  |                                             |                                             |                                            |                                            |                                            |                                            |                                   |                           |                                  |
| VIETNAM | Product License Number: 220002518/PCBB-HCM                                                                                              | Product License Number: 220002519/PCBB-HCM                                                                                                                                                                                                                                                                                                       | Product License Number: 220002520/PCBB-HCM  | Product License Number: 220002521/PCBB-HCM  | Product License Number: 220003108/PCBB-HCM | Product License Number: 250000983/PCBB-HCM | Product License Number: 250000985/PCBB-HCM | Product License Number: 250000984/PCBB-HCM | Not Available                     |                           |                                  |
|         | REGISTRANT:<br><br>Asia Actual Vietnam Co., LTD.<br>45/90 Binh Tien, Ward 7, District 6, Ho Chi Minh City, Vietnam<br><br>+84 969159420 |                                                                                                                                                                                                                                                                                                                                                  |                                             |                                             |                                            |                                            |                                            |                                            |                                   |                           |                                  |

Table B - Cycle Tracking App

| Feature | Cycle Tracking App                                                                                                                                                                                                                                                                                                                                                                                                                                             |    |     |
|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|-----|
| US      | <br>Apple Inc.<br>One Apple Park Way Cupertino, CA 95014 <a href="http://www.apple.com">www.apple.com</a><br><b>Contact:</b> <a href="mailto:medicalcompliance@group.apple.com">medicalcompliance@group.apple.com</a>                                                                                                                                                         |    |     |
| EU      | <table border="1"><tr><td>EU</td><td>REP</td></tr></table><br>Apple Distribution International<br>Hollyhill Industrial Estate,<br>Hollyhill, Cork,<br>Ireland<br><br>Contact: <a href="mailto:medicalcompliance@group.apple.com">medicalcompliance@group.apple.com</a><br><br> 0123<br><br> | EU | REP |
| EU      | REP                                                                                                                                                                                                                                                                                                                                                                                                                                                            |    |     |

| Feature | Cycle Tracking App                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |    |     |
|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|-----|
| ISRAEL  | <table><tr><td>IL</td><td>REP</td></tr></table> <p>Medogar Medical Equipment Ltd.<br/>Hasadna St. 8 P.O.B 2586 Ra'annana 4365104 ISRAEL<br/>Office Tel: +972-9-7401457<br/>Fax: +972-9-7401459</p> <p>מדוגר מכשור רפואי בע"מ<br/>הסדנא 8 ת.ד. 2566 רעננה 4365104<br/>טל: 09-7401457<br/>פקס: 09-7401459</p> <p>ميدوگار للأجهزة الطبية المحدودة<br/>شارع هاسادنا 8، ص.ب. 2566<br/>رعننا 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> | IL | REP |
| IL      | REP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |    |     |
| MOLDOVA | <table><tr><td>MD</td><td>REP</td></tr></table> <p>AUTHORIZED REPRESENTATIVE:</p> <p>JERELO S.R.L.<br/>MD-2024, str. Pietrăriei, nr 19A, of. 3.<br/>mun. Chişinău, Republica Moldova<br/>+37378538295</p>                                                                                                                                                                                                                                                                                                                                                                     | MD | REP |
| MD      | REP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |    |     |

| Feature                  | Cycle Tracking App                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |    |     |
|--------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|-----|
| <b>REPUBLIC OF KOREA</b> | <p>본 앱은 “의료기기” 임.</p> <p>수입업자: 이머고코리아 (유)<br/>06236) 서울특별시 강남구 테헤란로 152 강남파이낸스센터 26층<br/>제조원: Apple Inc.<br/>(본사) One Apple Park Way, Cupertino, CA 95014, USA<br/>(공장) 20450 Stevens Creek Blvd., Cupertino, CA 95014, USA</p> <p>허가번호: 수허 24-33 호</p> <p>명칭 (제품명, 품목명, 모델명): 이머고코리아(유)-생식력 진단보조 소프트웨어, Cycle Tracking (CT)<br/>소프트웨어 비교: 4.x<br/>포장단위: 1ea</p> <p>사용목적 :<br/>14세 이상 여성을 대상으로 사용자 생리 주기, 배란 테스트 결과 입력과 함께 심박 수 및 손목 온도의 변화를 분석하여 생리 주기를 추적 및 예측하고, 이것을 통해 사용자가 임신계획을 세우는데 사용되는 소프트웨어</p> |    |     |
| <b>SWITZERLAND</b>       | <table border="1" data-bbox="651 766 804 815"> <tr> <td>CH</td><td>REP</td></tr> </table> <p><b>CH-REP:</b></p> <p>QUNIQUE GmbH<br/>Bahnhofweg 17<br/>5610 Wohlen<br/>Switzerland</p>                                                                                                                                                                                                                                                                                                                     | CH | REP |
| CH                       | REP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |    |     |

| Feature | Cycle Tracking App                                                                                                                                                                                                                                                                                                                                  |
|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| UKRAINE | <div><div>UA</div><div>REP</div></div> <p>ТОВ «ДЖЕРЕЛО-УКРАЇНА»<br/>01033, Україна, м. Київ, вулиця Шота Руставелі 33-Б, офіс 27</p> <p>e-mail: <a href="mailto:uarep@jerelo.eu">uarep@jerelo.eu</a><br/>тел. +38 (044) 360 30 11</p> <div></div> <p>UA.TR.120</p> |

**EQUIPMENT SYMBOLS**

Manufacturer



Consult instructions for use



Authorized Representative



Medical Device



Importer

