# RED Declaration of Conformity

Abbott Medical hereby declares that the following product(s) conform to the applicable provisions of the Radio Equipment Directive (2014/53/EU). All supporting documentation is retained under the premises of Abbott Medical. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

| | |
|---|---|
| **Manufacturer Address:** | Abbott Medical<br>15900 Valley View Court<br>Sylmar, CA 91342<br>USA<br><br>Abbott Medical<br>Lot A Interior - #2 Rd Km. 67.5, Santana Industrial Park,<br>Arecibo, PR 00612<br>USA<br><br>Abbott Medical Plot 102, Lebuhraya Kampung Jawa,<br>Bayan Lepas Industrial Zone, 11900 Penang<br>Malaysia |
| **European Representative** | Abbott Medical<br>The Corporate Village Da Vincilaan 11 Box F1,<br>1935 Zaventem, Belgium |
| **Product Type:** | Implantable Cardioverter/Defibrillators |
| **Applicable Standards:** | 3.1a:<br>EN 62311:2008, EN 62479:2010, SAR:1999/519/EC<br>EN45502-1:2015, EN 45502-2-2:2008, ISO 14708-6:2010,<br>ISO14117:2019<br><br>3.1b:<br>EN45502-1:2015, EN 45502-2-2:2008 ISO14117:2019, EN 60601-1-2:2015,<br>EN 301 489-1 V2.1.1 (2017-02),<br>EN 301 489-31 V2.2.1 (2019-04),<br>EN 301 489-17 V3.2.4 (2020-09),<br>EN 301 489-27 V2.2.1 (2019-04)<br><br>3.2:<br>EN 302 195 V2.1.1 (2016-06)<br>EN 300 328 V2.2.2 (2016-11)<br>EN 301 839 V2.1.1.(2016-04) |
| **Applicable Annex:** | III |
| **Notified Body:** | TUV SUD America 1929 performed a conformity assessment of the technical construction file. |
| **Certificate:** | CB-20-0226 i01 |
| **Technical Construction File:** | 60085281 |

**Signature:**

Colleen Canan, DVP Regulatory Affairs

September 14, 2022
Issue Date

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| Product Name (s) | Model # | Description of accessories and components: |
|---|---|---|
| Ellipse™ VR | CD1377-36 | **IMPLANTABLE SINGLE CHAMBER AND DUAL CHAMBER DEFIBRILLATORS**<br>The Implantable Cardioverter Defibrillator (ICD) devices are primarily intended for use with compatible leads to detect and treat life threatening ventricular arrhythmias by providing ventricular antitachycardia pacing, and ventricular cardioversion/defibrillation. In addition, ICD devices can detect and treat<br><br>• chronic symptomatic bradyarrhythmia by providing sensing and pacing in the right ventricle<br>• various atrioventricular conduction abnormalities by providing sensing and pacing in the right ventricle and/or right atrium<br><br>**IMPLANTABLE TRIPLE CHAMBER DEFIBRILLATORS**<br>The Cardiac Resynchronization Therapy Defibrillator (CRT-D) devices are primarily intended for use with compatible leads to detect and treat life threatening ventricular arrhythmias by providing ventricular antitachycardia pacing, and ventricular cardioversion/defibrillation. In addition, these devices can detect and treat chronic symptomatic bradyarrhythmia by providing sensing and pacing in the right ventricle and various atrioventricular conduction abnormalities by providing sensing and pacing in the right ventricle and/or right atrium.<br><br>CRT-D devices sense cardiac activity and provide pacing to resynchronize the right and left ventricles. |
| Ellipse™ VR | CD1377-36C | |
| Ellipse™ VR | CD1377-36Q | |
| Ellipse™ VR | CD1377-36QC | |
| Ellipse™ DR | CD2377-36C | |
| Ellipse™ DR | CD2377-36QC | |
| Fortify™ VR | CD1233-40 | |
| Fortify™ VR | CD1233-40Q | |
| Fortify Assura™ VR | CD1359-40 | |
| Fortify Assura™ VR | CD1359-40C | |
| Fortify Assura™ VR | CD1359-40Q | |
| Fortify Assura™ VR | CD1359-40QC | |
| Fortify™ DR | CD2233-40 | |
| Fortify™ DR | CD2233-40Q | |
| Fortify Assura™ DR | CD2359-40 | |
| Fortify Assura™ DR | CD2359-40C | |
| Fortify Assura™ DR | CD2359-40Q | |
| Fortify Assura™ DR | CD2359-40QC | |
| Unify™ | CD3235-40 | |
| Unify™ | CD3235-40Q | |
| Unify Quadra™ | CD3251-40 | |
| Unify Quadra™ | CD3251-40Q | |
| Unify Assura™ | CD3361-40 | |
| Unify Assura™ | CD3361-40C | |
| Unify Assura™ | CD3361-40Q | |
| Unify Assura™ | CD3361-40QC | |
| Quadra Assura™ | CD3367-40C | |
| Quadra Assura™ | CD3367-40QC | |
| Quadra Assura MP™ | CD3371-40 | |
| Quadra Assura MP™ | CD3371-40C | |
| Quadra Assura MP™ | CD3371-40Q | |
| Quadra Assura MP™ | CD3371-40QC | |