

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:

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15900 Valley View Court
Sylmar, CA 91342
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Abbott Medical
Lot A Interior - #2 Rd Km. 67.5, Santana Industrial Park,
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Malaysia

European Representative

Abbott Medical
The Corporate Village Da Vincilaan 11 Box F1,
1935 Zaventem, Belgium

Product Type:

Implantable Cardioverter/Defibrillators

Applicable Standards:

3.1a:
EN 62311:2008, EN 62479:2010, SAR:1999/519/EC
EN45502-1:2015, EN 45502-2-2:2008, ISO 14708-6:2010,
ISO14117:2019

3.1b:
EN45502-1:2015, EN 45502-2-2:2008 ISO14117:2019, EN
60601-1-2:2015,
EN 301 489-1 V2.1.1 (2017-02),
EN 301 489-31 V2.2.1 (2019-04),
EN 301 489-17 V3.2.4 (2020-09),
EN 301 489-27 V2.2.1 (2019-04)

3.2:
EN 302 195 V2.1.1 (2016-06)
EN 300 328 V2.2.2 (2016-11)
EN 301 839 V2.1.1.(2016-04)

Applicable Annex:

III

Notified Body:

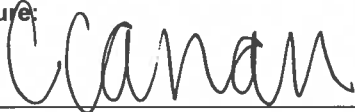
TUV SUD America 1929 performed a conformity assessment of the technical construction file.

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 Ellipse™ VR Ellipse™ VR Ellipse™ VR Ellipse™ DR Ellipse™ DR	CD1377-36 CD1377-36C CD1377-36QC CD1377-36QC CD2377-36C CD2377-36QC	IMPLANTABLE SINGLE CHAMBER AND DUAL CHAMBER DEFIBRILLATORS 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 <ul style="list-style-type: none"> • chronic symptomatic bradyarrhythmia by providing sensing and pacing in the right ventricle • various atrioventricular conduction abnormalities by providing sensing and pacing in the right ventricle and/or right atrium
Fortify™ VR Fortify™ VR Fortify Assura™ VR Fortify Assura™ VR Fortify Assura™ VR Fortify Assura™ VR Fortify™ DR Fortify™ DR Fortify Assura™ DR Fortify Assura™ DR Fortify Assura™ DR Fortify Assura™ DR	CD1233-40 CD1233-40Q CD1359-40 CD1359-40C CD1359-40Q CD1359-40QC CD2233-40 CD2233-40Q CD2359-40 CD2359-40C CD2359-40Q CD2359-40QC	IMPLANTABLE TRIPLE CHAMBER DEFIBRILLATORS 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. CRT-D devices sense cardiac activity and provide pacing to resynchronize the right and left ventricles.
Unify™ Unify™ Unify Quadra™ Unify Quadra™ Unify Assura™ Unify Assura™ Unify Assura™ Unify Assura™ Quadra Assura™ Quadra Assura™ Quadra Assura MP™ Quadra Assura MP™ Quadra Assura MP™ Quadra Assura MP™	CD3235-40 CD3235-40Q CD3251-40 CD3251-40Q CD3361-40 CD3361-40C CD3361-40Q CD3361-40QC CD3367-40C CD3367-40QC CD3371-40 CD3371-40C CD3371-40Q CD3371-40QC	(Continued from previous row)