ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 17 07 14607 216

Manufacturer:

St. Jude Medical
Cardiac Rhythm Management
Division
15900 Valley View Court
Sylmar, CA 91342
USA

EC-Representative:

St. Jude Medical
Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
BELGIUM

Product: **Implantable Cardioverter / Defibrillators**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 certificate is mandatory. See also notes overleaf.

Report no.: 713106728

Valid from: 2017-09-26
Valid until: 2022-09-25

Date, 2017-09-25

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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Product Service

EC Certificate
EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 17 07 14607 216

Model(s): **see attachment**

Parameters: ./.

Facility(ies):

St. Jude Medical Cardiac Rhythm Management Division
15900 Valley View Court, Sylmar, CA 91342, USA

St. Jude Medical Puerto Rico LLC
Lot A Interior - #2 Rd Km. 67.5, Santana Industrial Park, Arecibo
PR 00612, USA

St. Jude Medical Operations (M) Sdn.Bhd.
Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas Industrial
Zone, 11900 Penang, MALAYSIA

St. Jude Medical Coordination Center BVBA
European Distribution Center, BruCargo 831, 1931 BruCargo,
BELGIUM

Design Facility(ies):

St. Jude Medical Cardiac Rhythm Management Division
15900 Valley View Court, Sylmar, CA 91342, USA

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Product Service

Attachment for Certificate no I7 17 07 14607 216
dated 2017-09-25

Product: **Implantable Cardioverter / Defibrillators**

Test Report No.: 71362982

Model:	**Model No:**
Fortify™ VR	CD1233-40, CD1233-40Q
Fortify™ DR	CD2233-40, CD2233-40Q
Unify™	CD3235-40, CD3235-40Q

Test Report No.: 71376924

Unify Quadra™	CD3251-40, CD3251-40Q

Test Report No.: 713000600 / 713000540

Ellipse™ VR	CD1275-36, CD1275-36Q,
Ellipse™ DR	CD2275-36, CD2275-36Q,

Test Report No.: 713015987_1

Quadra Assura™	CD3367-40, CD3367-40C
Quadra Assura MP™	CD3371-40, CD3371-40C
Unify Assura™	CD3361-40, CD3361-40C CD3361-40Q, CD3361-40QC
Fortify Assura™ DR	CD2359-40, CD2359-40C
Fortify Assura™ VR	CD1359-40, CD1359-40C
Ellipse™ DR	CD2377-36, CD2377-36C
Ellipse™ VR	CD1377-36, CD1377-36C

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Product Service

Attachment for Certificate no I7 17 07 14607 216
dated 2017-09-25

Test Report No.: 713015987_1 / 713057341

Model:	**Model No:**	**Variants:**
Ellipse™ VR	CD1377-36Q, CD1377-36QC	MR Conditional
Ellipse™ DR	CD2377-36Q, CD2377-36QC	MR Conditional

Test Report No.: 713015987_1 / 713060615

Fortify Assura™ VR	CD1359-40Q, CD1359-40QC	MR Conditional
Fortify Assura™ DR	CD2359-40Q, CD2359-40QC	MR Conditional

Test Report No.: 713015987_1 / 713068024

Quadra Assura™	CD3367-40Q, CD3367-40QC	MR Conditional
Quadra Assura MP™	CD3371-40Q, CD3371-40QC	MR Conditional

Munich, MHS-CRT, 2017-09-25

Stefan Preiß
Certification Medical Technology

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