ST. JUDE MEDICAL

SJM Declaration of Conformity
Implantable Cardioverter/Defibrillators

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex 2 of the European Union's Active Implantable Medical Devices Directive, AIMDD, 90/385/EEC. All supporting documentation is retained under the premises of SJM. We declare no application has been lodged with any other notified body for the same products. 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:	*St. Jude Medical Cardiac Rhythm Management Division* *15900 Valley View Court* *Sylmar, CA 91342, USA*
European Representative:	St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
Product Type:	Implantable Cardioverter/Defibrillators
Product Name(s):	See Attachment
Model Number(s):	*See Attachment*
Classification:	AIMD
GMDN Code(s):	*See Attachment*
Original CE Mark Date:	*See Attachment*
Certificate No. and expiration date:	EC Certification No: I7 17 07 14607 216 Expiration Date: 2022-09-25 FQA Certificate No: I1 014607 0211 Rev. 01 Expiration Date: 2024-05-26 EN ISO 13485:2016 Certificate No: Q5 014607 0231 Rev. 00 Expiration Date: 2022-03-31

Signature:

Kathy Berg

Kathy Berg
Sr. Manager Regulatory Affairs

22APR2020
Issue Date

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Applicable Quality System Standards:	Fulfills the requirements of Annex 2 of the European Union's Active Medical Devices Directive, AIMDD, 90/385/EEC/corresponding national legislation Fulfills applicable requirements including CE marking and the Essential Requirements of AIMDD, 90/385/EEC/corresponding national legislation
Notified Body:	TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstraße 65, 80339, Münich, Germany
Notified Body Number:	0123
Manufacturing Facilities:	*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 00162, USA* *St. Jude Medical Operations (M) Sdn.Bhd Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas Industrial Zone, 11900 Penang, MALAYSIA*

Signature:

Kathy Berg

Sr. Manager Regulatory Affairs

22 APR 2020

Issue Date

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ATTACHMENT TO DECLARATION OF CONFORMITY

The following product(s) is/are approved under EC-Certificate number **I7 17 07 14607 216.**

Product Name	Model No.	GMDN Code	First Date of CE Marking
Fortify™ VR	CD1233-40, CD1233-40Q	35852	2010-1-29
Fortify™ DR	CD2233-40, CD2233-40Q	37265	2010-1-29
Unify™	CD3235-40, CD3235-40Q	47270	2010-1-29
Unify Quadra™	CD3251-40, CD3251-40Q	47270	2011-3-15
Ellipse™ VR	CD1275-36, CD1275-36Q	35852	2012-2-3
Ellipse™ DR	CD2275-36, CD2275-36Q	37265	2012-2-3
Quadra Assura™	CD3367-40, CD3367-40C	47270	2012-12-18
Quadra Assura MP™	CD3371-40, CD3371-40C	47270	2012-12-18
Unify Assura™	CD3361-40, CD3361-40C CD3361-40Q, CD3361-40QC	47270	2012-12-18
Fortify Assura™ DR	CD2359-40, CD2359-40C	37265	2012-12-18
Fortify Assura™ VR	CD1359-40, CD1359-40C	35852	2012-12-18
Ellipse™ DR	CD2377-36, CD2377-36C	37265	2012-12-18
Ellipse™ VR	CD1377-36, CD1377-36C	35852	2012-12-18
Ellipse™ VR	CD1377-36Q, CD1377-36QC MR Conditional	35852	2015-05-11
Ellipse™ DR	CD2377-36Q, CD2377-36QC MR Conditional	37265	2015-05-11
Fortify Assura™ VR	CD1359-40Q, CD1359-40QC MR Conditional	35852	2015-7-14
Fortify Assura™ DR	CD2359-40Q, CD2359-40QC MR Conditional	37265	2015-7-14
Quadra Assura™	CD3367-40Q, CD3367-40QC MR Conditional	47270	2015-10-13
Quadra Assura MP™	CD3371-40Q, CD3371-40QC MR Conditional	47270	2015-10-13

Signature:

Kathy Berg

Kathy Berg
Sr. Manager Regulatory Affairs

22APR2020
Issue Date