SJM Declaration of Conformity
Pacing System Analyzer and their Auxiliary Components

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:	Pacing System Analyzer and their Auxiliary Components
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 014607 0235 Rev. 01 Expiration Date: 2024-05-26 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
Sr. Manager Regulatory Affairs

8 Jun 2020
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*

Signature:

Kathy Berg
Sr. Manager Regulatory Affairs

8 Jun 2020
Issue Date

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ATTACHMENT TO DECLARATION OF CONFORMITY

The following product(s) is/are approved under EC Certificate Number **I7 014607 0235 Rev. 01.**

Product Name	Model Number	GMDN Code	First Date of CE Marking
Disposable surgical cable	4161	47143	2009-9-1
Merlin PSA	EX3100	31700	2010-3-4
Merlin PSA Cable Adapter	EX3170	31700	2010-3-4
Merlin PSA "M" Adapter	EX3180	31700	2010-3-4
Merlin Antenna Adapter	EX3190	31700	2010-3-4
Disposable surgical cable	4051L	47143	2012-2-24
Merlin PSA Patient Cable	EX3150	47143	2010-12-09

Signature:

Kathy Berg
Sr. Manager Regulatory Affairs

Issue Date