



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

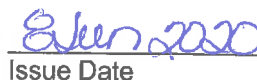
FQA
Certificate No: I1 014607 0211 Rev. 01
Expiration Date: 2024-05-26

EN ISO 13485:2016
Certificate No: Q5 014607 0231 Rev. 00
Expiration Date: 2022-03-31

Signature:


Kathy Berg

Sr. Manager Regulatory Affairs


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, München, 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

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