



**SJM Declaration of Conformity
Implantable Pacemakers
ATTACHMENT TO DECLARATION OF CONFORMITY**

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex 2 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*

European Representative: *St. Jude Medical Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem, Belgium*

Product Type: *Implantable Pacemakers*

Product Name(s): *See Attachment*

Model Number(s): *See Attachment*

Classification: *AIMD*

GMDN Code(s): *See Attachment*

Original CE Mark Date: *See Attachment*

(FQA or EC as appropriate) Certificate No and expiration date: *EC
Certification No: I7 014607 0234 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

Kathy Berg
Sr. Manager Regulatory Affairs

22 APR 2020

Issue Date

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Applicable Quality System Standards:

Fulfills the requirements of Annex 2 of the European Union's Active Implantable Medical Devices Directive, AIMDD, 90/385/EEC and corresponding national legislation.

Fulfills applicable requirements including CE marking and the Essential Requirements of the AIMDD, 90/385/EEC and 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*

*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*

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The following product(s) is/are approved under EC-certificate number I7 014607 0234 Rev. 01:

Table with 4 columns: Product Name, Model No., GMDN Codes, and First Date of CE Marking. It lists various pacemaker models such as Microny, Zephyr, Assurity, Endurity, Allure, and Zenex with their respective GMDN codes and CE marking dates.

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Product Name	Model No.	GMDN Codes	First Date of CE Marking
Zenex MRI™	PM2282 (MR Conditional)	47265	2018-10-12
Zenus MRI™	PM1182 (MR Conditional)	47267	2018-10-12
Zenus MRI™	PM2182 (MR Conditional)	47265	2018-10-12
Verity™ ADx XL VDR	5456	47265	2003-8-22

Signature:

Kathy Berg
Sr. Manager Regulatory Affairs

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