



SJM Declaration of Conformity Leads for Brady IPGs 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 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: *Leads for Brady IPGs 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 Nos. and expiration dates: *EC
Certification No: I7 014607 0200 Rev. 01
Expiration Date: 2024-01-20*

*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*

Signature:

Kathy Berg
Sr. Manager Regulatory Affairs



Issue Date

SJM Declaration of Conformity
Leads for Brady IPGs and Their Auxiliary Components
ATTACHMENT TO DECLARATION OF CONFORMITY

The following product(s) is/are approved under EC-certificate number I7 014607 0200 Rev. 01:

Product Name	Model No.	Length	GMDN Codes	First Date of CE Marking
AV Plus® DX	1368	52, 58, 65	35223	20-Jan-1999
IsoFlex™	1944 (MR Conditional)	46, 52	35223	2-Feb-2015
IsoFlex™	1948 (MR Conditional)	52, 58	35223	2-Feb-2015
OptiSense™	1999	46, 52	35223	29-Apr-2008
Quartet	1456Q	75	35223	18-Dec-2015
Quartet	1456Q (MR Conditional)	86	35223	18-Dec-2015
Quartet	1457Q	75	35223	18-Dec-2015
Quartet	1457Q (MR Conditional)	86	35223	18-Dec-2015
Quartet	1458Q	75	35223	30-Sep-2009
Quartet	1458Q (MR Conditional)	86	35223	13-Oct-2015
Quartet	1458Q	92	35223	30-Sep-2009
Quartet	1458QL	75	35223	18-Dec-2015
Quartet	1458QL (MR Conditional)	86	35223	18-Dec-2015
QuickFlex™ µ	1258T	75, 86, 92	35223	29-Sep-2008
Tendril™ MRI	LPA1200M (MR Conditional)	46, 52, 58	35223	23-Feb-2011
Tendril™ STS	2088TC	65, 100	35223	16-Jun-2009
Tendril™ STS	2088TC (MR Conditional)	46, 52, 58	35223	2-Feb-2015

Signature:



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