

SJM Declaration of Conformity Leads for Tachy 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 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: *Leads for Tachy 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 No. and expiration date: *EC Certification No: I7 014607 0194 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*

*St. Jude Medical Puerto Rico LLC
Lot A Interior - #2 Rd Km. 67.5, Santana Industrial Park,
Arecibo PR 00162, US*

*St. Jude Medical Operations (M) Sdn.Bhd
Plot 102, Ledbuhaya Kampung Jawa, Bayan Lepas
Industrial Zone, 11900 Penang, MALAYSIA*

Signature:

Kathy Berg
Sr. Manager Regulatory Affairs



Issue Date



**SJM Declaration of Conformity
Leads for Tachy IPGs and their Auxiliary Components
ATTACHMENT TO DECLARATION OF CONFORMITY**

The following product(s) is/are approved under EC Certificate Number I7 014607 0194 Rev. 01.

Product Name	Lead Model	Length (cm)	GMDN Code	First Date of CE Marking
Durata	7120, 7121, 7122	60, 65, 75	35853	2007-11-23
	7170, 7171	60, 65, 75		
	7120Q	52		2009-09-01
	7120Q	58 (MR Conditional) 65 (MR Conditional)		2015-05-11
	7121Q	52, 58, 65		2009-09-01
	7122Q	52		2009-09-01
	7122Q	58 (MR Conditional) 65 (MR Conditional)		2015-05-11
	7170Q, 7171Q, 7172Q	52, 58, 65		2009-09-01
Optisure	LDA210, LDA220, LDA230	60, 65, 75		2012-12-19
	LDP220 LDP230	60, 65, 75		2012-12-19

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Product Name	Lead Model	Length (cm)	GMDN Code	First Date of CE Marking
Optisure	LDA220Q	52	35853	2012-12-19
	LDA220Q	58 (MR Conditional) 65 (MR Conditional)		2015-05-11
	LDA230Q	52, 58, 65		2012-12-19
	LDA210Q	52		2012-12-19
	LDA210Q	58 (MR Conditional) 65 (MR Conditional)		2015-05-11
	LDP210Q, LDP220Q, LDP230Q	52, 58, 65		2012-12-19

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