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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-200.14.03



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 014607 0200 Rev. 01

Manufacturer: **St. Jude Medical
Cardiac Rhythm Management
Division**
15900 Valley View Court
Sylmar CA 91342
USA

EC-Representative: St. Jude Medical Coordination Center BVBA
The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem,
BELGIUM

Product: **Leads for Brady IPGs and their auxiliary
components**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 certificate is mandatory. See also notes overleaf.

Report no.: 713136639

Valid from: 2019-01-21

Valid until: 2024-01-20

Date, 2019-01-17

Stefan Preiß



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Model(s):

see next page

Facility(ies):

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

Design Facility(ies)

St. Jude Medical Cardiac Rhythm Management Division,
15900 Valley View Court, Sylmar, CA 91342, USA

Parameters:

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Product: Leads for Brady IPGs and their auxiliary components

Test Report No.: 71346063

Model:	Model No:	Length: [cm]	Variant:
AV Plus® DX	1368	52 58 65	

Test Report No.: 71333914

Model:	Model No:	Length: [cm]	Variant:
OptiSense™	1999	46 52	

Test Report No.: 71336638

Model:	Model No:	Length: [cm]	Variant:
QuickFlex™μ	1258T	75 86 92	

Test Report No.: 71355744

Model:	Model No:	Length: [cm]	Variant:
Quartet	1458Q	75 92	



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Test Report No.: 71351838

Model:	Model No:	Length: [cm]	Variant:
Tendril™ STS	2088TC	65 100	

Test Report No.: 713035264

Model:	Model No:	Length: [cm]	Variant:
Tendril™ STS	2088TC	46 52 58	MR Conditional MR Conditional MR Conditional
IsoFlex™	1944	46 52	MR Conditional MR Conditional
	1948	52 58	MR Conditional MR Conditional

Test Report No.: 71355744/ 713068024

Model:	Model No:	Length: [cm]	Variant:
Quartet	1458Q	86	MR Conditional

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 ZERTIFIKAT ◆ CERTIFICATE ◆ 認 證 證 書 ◆ CERTIFICADO ◆ CERTIFICAT



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No. I7 014607 0200 Rev. 01

Test Report No.: 713068167

Model:	Model No:	Length: [cm]	Variant:
Quartet	1456Q	75	MR Conditional
		86	
	1457Q	75	MR Conditional
		86	
	1458QL	75	MR Conditional
		86	

Test Report No.: 713097198

Model:	Model No:	Length: [cm]	Variant:
Tendril MRI	LPA1200M	46	MR Conditional
		52	MR Conditional
		58	MR Conditional

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