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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 0234 Rev. 01

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

Product: **Implantable Pacemakers**

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.: 713167182

Valid from: 2019-08-30
Valid until: 2024-05-26

Date, 2019-08-30

Stefan Preiß
Head of Certification/Notified Body

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Model(s): see below

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

Parameters ./.

Design Facility(ies): St. Jude Medical Cardiac Rhythm Management Division
15900 Valley View Court, Sylmar, CA 91342, USA

Product: Implantable Pacemakers

Test Report No.: 70069297

Model: **Model No.:** **Variant:**

Microny™ II SR+ 2525T

Test Report No.: 70110810

Model: **Model No.:** **Variant:**

Zephyr™ SR 5620

Zephyr™ DR 5820

Zephyr™ XL DR 5826

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Test Report No.: 71321436

Model:	Model No.:	Variant:
Zephyr™ XL SR	5626	

Test Report No.: 713017309_1

Model:	Model No.:	Variant:
Assurity™	PM1240	
Assurity™	PM2240	
Endurity™	PM1160	
Endurity™	PM2160	
Allure™	PM3120	
Allure™ RF	PM3222	
Allure Quadra™ RF	PM3242	

Test Report No.: 713028360

Model:	Model No.:	Variant
Quadra Allure MP™RF	PM3262	

Test Report No.: 713043621

Model:	Model No.:	Variant:
Assurity MRI™	PM1272	MR Conditional
Assurity MRI™	PM2272	MR Conditional
Endurity MRI™	PM1172	MR Conditional
Endurity MRI™	PM2172	MR Conditional
Endurity™	PM1162	MR Conditional
Endurity™	PM2162	MR Conditional



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Test Report No.: 713057320

Model:	Model No.:	Variant:
Endurity™ Core	PM1140	MR Conditional
Endurity™ Core	PM2140	MR Conditional
Endurity™ Core	PM1152	MR Conditional
Endurity™ Core	PM2152	MR Conditional

Test Report No.: 713084189

Model:	Model No.:	Variant:
Quadra Allure™	PM3542	MR Conditional
Quadra Allure MP™	PM3562	MR Conditional

Test Report No.: 713130819

Model:	Model No.:	Variant:
Zenex™	PM1250	
Zenex™	PM2250	
Zenus™	PM1170	
Zenus™	PM2170	
Zenex MRI™	PM1282	MR Conditional
Zenex MRI™	PM2282	MR Conditional
Zenus MRI™	PM1182	MR Conditional
Zenus MRI™	PM2182	MR Conditional

Test Report No.: 713167182

Model:	Model No.:	Variant:
Verity™ ADx XL VDR	5456	

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