



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 14 05 14607 174

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: **Implantable Pacemaker Systems
with a conditional intended use in
a MRI environment**

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.: 713034106

Valid from: 2014-07-16

Valid until: 2017-04-22

Date, 2014-07-17

Hans-Heiner Junker



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Model(s): see attachment

Parameters:

- Static magnetic field strength of 1.5 Tesla (T) only
- Maximum gradient slew rate of 200T/m/s per axis
- Horizontal closed bore clinical scanner working in the Normal Operating Mode or First Level Controlled Operating Mode,
- whole body specific absorption rate (SAR) = 4.0 W/kg
- head SAR = 3.2 W/kg

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

**Attachment for Certificate no I7 14 05 14607 174
dated 2014-07-16****Product: Implantable Pacemaker Systems with a conditional
intended use in a MRI environment**

Test Report No.: 71374849

The following products are designed/manufactured in the facility(ies)

- St. Jude Medical, CRMD, 15900 Valley View Court, Sylmar, CA 91342, USA (Design/Manufacturing)
- St. Jude Medical Puerto Rico LLC, Lot A Interior - #2 Rd Km. 67.5, Santana Industrial Park, Arecibo PR 00612, USA (Manufacturing)
- St. Jude Medical Operations (M) Sdn. Bhd., Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas Industrial Zone, 11900 Penang, MALAYSIA (Manufacturing)

Model:**Model no.:**Accent MRI™
Accent™ ST MRIPM1224, PM2224
PM1226, PM2226

Test Report No.: 71370731

The following products are designed/manufactured in the facility(ies)

- St. Jude Medical, CRMD, 15900 Valley View Court, Sylmar, CA 91342, USA (Design/Manufacturing)
- St. Jude Medical Puerto Rico LLC, Lot A Interior - #2 Rd Km. 67.5, Santana Industrial Park, Arecibo PR 00612, USA (Manufacturing)
- St. Jude Medical Operations (M) Sdn. Bhd., Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas Industrial Zone, 11900 Penang, MALAYSIA (Manufacturing)

Model:**Model no.:**

Tendril MRI™

LPA1200M



**Attachment for Certificate no I7 14 05 14607 174
dated 2014-07-16**

Test Report No.: 71374851

The following products are designed/manufactured in the facility(ies)

- St. Jude Medical, CRMD, 15900 Valley View Court, Sylmar, CA 91342, USA (Design/Manufacturing)

Model:	Model no.:
SJM MRI Activator™ Handheld Device	EX4000

Test Report No.: 71385181

The following products are designed/manufactured in the facility(ies)

- St. Jude Medical, CRMD, 15900 Valley View Court, Sylmar, CA 91342, USA (Design/Manufacturing)
- St. Jude Medical Puerto Rico LLC, Lot A Interior - #2 Rd Km. 67.5, Santana Industrial Park, Arecibo PR 00612, USA (Manufacturing)
- St. Jude Medical Operations (M) Sdn.Bhd., Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas Industrial Zone, 11900 Penang, MALAYSIA (Manufacturing)

Model:	Model no.:
Accent MRI™	PM1124, PM2124
Accent™ ST MRI	PM1126, PM2126

Munich, CRT2, 2014-07-16

Hans-Heiner Junker
Certification Medical Technology