



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. 17 14 01 14607 170

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: **Auxiliary components for implantable leads**
Accessories for implantable Brady / Tachy
IPGs

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.: 713034638

Valid from: 2014-05-28

Valid until: 2019-05-27

Date, 2014-05-27

Hans-Heiner Junker



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

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No. 17 14 01 14607 170

Model(s): see attachment

Parameters: ./.

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

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



**Attachment for Certificate no I7 14 01 14607 170
dated 2014-05-28**

Product: Accessories for implantable Brady / Tachy IPGs

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

- St. Jude Medical, Cardiac Rhythm Management Division, 15900 Valley View Court
Sylmar, CA 91342, USA (Design/Manufacturing)

Model:	Model no.:
"L" Hex wrenches	437-246

Test Report No.: 70066003

Model:	Model no.:
Generic Torque Driver	AC-TD
Torque Driver	442-2
Magnet	AC-0160
DF-1 Receptable Plug	AC-DP-3

Test Report No.: 70113271

Model:	Model no.:
IS-1 Receptable Plug	AC-IP-2
Terminal caps	4033
Adapting sleeve kit	4023
Medical Adhesive	424
Guidewire	4078G
Stylet Kit	4078S



**Attachment for Certificate no I7 14 01 14607 170
dated 2014-05-28**

Test Report No.: 70066003

Model:	Model no.:
Silicon Oil	AC-0130
Suture Sleeve	TV-0700
Firm Stylet	S-60-F
Soft Stylet	S-65-S
Firm Stylet	S-65-F
Extra-Firm Stylet	S-65-X
Soft Stylet	S-75-S
Firm Stylet	S-75-F
Extra-Firm Stylet	S-75-X

Test Report No.: 70087329

Model:	Model no.:
Tip Introducer / Torque Tool Accessory Kit	4071

Test Report No.: 70117109

Model:	Model no.:
Stylet Kit	4090

Test Report No.: 71318970

Model:	Model no.:
Stylet, Extra Soft	S-65-XS

Test Report No.: 71356992

Model:	Model no.:
Mond™ RVOT Stylet Kits	4141, 4151, 4140, 4150



**Attachment for Certificate no I7 14 01 14607 170
dated 2014-05-28**

Test Report No.: 70111161

Model:	Model no.:
Lead Flushing Tools	FL-1056
Stylet Guide Funnel	421
Catheter Introducer (vein pick)	420
Slit Suture Sleeves	SS-1056

Test Report No.: 71356816

Model:	Model no.:
Stylet Kit	DS06003
Stylet Kit	DS06002

Test Report No.: 71358860

Model:	Model no.:
Lead Cap (IS-1/DF-1/SJ4)	4033A

Test Report No.: 71366048

Model:	Model no.:
Stylet Kit	DS06000
Stylet Kit	DS06001

Test Report No.: 71370455

Model:	Model no.:
Suture Sleeve	DS0A001
Slit Suture Sleeve	DSA0006



**Attachment for Certificate no I7 14 01 14607 170
dated 2014-05-28**

Test Report No.: 71391183

Model:

IS4/DF4 Port Plug

Model no.:

AC-IS4PP

Test Report No.: 71391164

Model:

IS4/DF4 Connector Sleeve

Model no.:

EX3151

Product: Auxiliary components for implantable leads

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

- St. Jude Medical, Cardiac Rhythm Management Division, 15900 Valley View Court
Sylmar, CA 91342, USA (Design/Manufacturing)

Test Report No.: 713000264

Model:

IS4 Flushing/Funneling Tool

Model no.:

DS0A002

Munich, CRT2, 2014-05-27

Hans-Heiner Junker
Certification Medical Technology