bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

St. Jude Medical Costa Rica Ltda.
Edificio #44
Calle O, Ave. 2, Zona Franca
El Coyol
ALAJUELA
Costa Rica

Holds Certificate Number: **MD 639058**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Manufacture and distribution of radio-frequency(RF) ablation catheters, electrophysiology (EP) catheters, intracardiac echocardiography catheters, cardiac mapping system accessories, transseptal access system, introducer catheters, diagnostic guidewire, vascular closure systems, and the design of cardiac mapping system accessories.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2015-08-19
Latest Revision Date: 2021-04-22

Effective Date: 2019-02-26
Expiry Date: 2021-12-13

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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-200.14.03

TÜV SÜD 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 0235 Rev. 01

Manufacturer:

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

Product:

Pacing System Analyzer 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.: 713174689

Valid from: 2020-05-28
Valid until: 2024-05-26

Date, 2020-05-28

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Product Service

EC Certificate

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(Other devices than custom made or intended for clinical investigation)

No. I7 014607 0235 Rev. 01

Model(s):	**see below**
Product:	**Pacing System Analyzer and their auxiliary components**

Test Report No.:	71327994
Model:	**Model no.:**
Disposable surgical cable	4161

Test Report No.:	71364725
Model:	**Model no.:**
Merlin PSA	EX3100
Merlin PSA Cable Adapter	EX3170
Merlin PSA "M" Adapter	EX3180
Merlin Antenna Adapter	EX3190

Test Report No.:	71394312
Model:	**Model no.:**
Disposable surgical cable	4051L

Test Report No.:	71372746, 713156176, 713174689
Model:	**Model no.:**
Merlin PSA Patient Cable	EX3150

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A4 / 07.17

Abbott Article 12 Declaration
EnSite Precision Surface Electrode Kit

Abbott Medical (Abbott) hereby declares that the following procedure pack conforms to the applicable provisions of Article 12 of the Medical Device Directive (MDD) 93/42/EEC. All supporting documentation is retained under the premises of Abbott. This declaration is issued under the sole responsibility of the assembler. This declaration supersedes any declaration issued previously for the same product(s).

Assembler:	St. Jude Medical Costa Rica Ltda. Edificio #44 Calle 0, Ave. 2 Zona Franca Coyol El Coyol, Alajuela, Costa Rica
Statements:	Abbott has verified the, mutual compatibility of the devices in accordance with the manufacturers' instructions and has carried out his operations in accordance with these instructions. Abbott has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers. The whole activity is subjected to appropriate methods of internal control and inspection.
Kit Name and Model Numbers	EnSite Precision Surface Electrode Kit
Applicable Quality System Standards:	ISO 13485:2016 MD 639058
Basic UDI	DMS-0039

See Kit Details beginning Page 2

Signature:

Jack Kromenhoek
Director, Regulatory Affairs

19 MAR 2020
Issue Date

Abbott Article 12 Declaration
EnSite Precision Surface Electrode Kit

Model EN0020-P, EnSite Precision Surface Electrode Procedure Pack

Device Name	Model Number	Class	Manufacturer	CE Certificate
EnSite Locating Electrodes	SURF-ELEC-2PRS	MDR Class I	St. Jude Medical Costa Rica Ltda. Edificio #44 Calle 0, Ave. 2 Zona Franca Coyol El Coyol, Alajuela, Costa Rica	N/A
EnSite System Reference Electrode	SYS-REF-V1	MDR Class I	St. Jude Medical Costa Rica Ltda. Edificio #44 Calle 0, Ave. 2 Zona Franca Coyol El Coyol, Alajuela, Costa Rica	N/A
3M Red Dot Radiolucent Monitoring Electrodes	2570-5	MDD Class I	3M Health Care 2510 Conway Avenue St. Paul, MN 55144-1000 USA	N/A

Signature:

Jack Kromenhoek
Director, Regulatory Affairs

19 MAR 2020
Issue Date

ST. JUDE MEDICAL

90264652 Rev. H

Declaration of Conformity

SJM Declaration of Conformity
Pacing System Analyzer 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:	Pacing System Analyzer 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 0235 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

8 Dec 2020
Issue Date

SJM Declaration of Conformity
Pacing System Analyzer and their Auxiliary Components

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, Münich, Germany
Notified Body Number:	0123
Manufacturing Facilities:	*St. Jude Medical Cardiac Rhythm Management Division 15900 Valley View Court Sylmar, CA 91342, USA*

Signature:

Kathy Berg

Kathy Berg
Sr. Manager Regulatory Affairs

8 Jun 2020

Issue Date

SJM Declaration of Conformity
Pacing System Analyzer and their Auxiliary Components
ATTACHMENT TO DECLARATION OF CONFORMITY

The following product(s) is/are approved under EC Certificate Number **I7 014607 0235 Rev. 01.**

Product Name	Model Number	GMDN Code	First Date of CE Marking
Disposable surgical cable	4161	47143	2009-9-1
Merlin PSA	EX3100	31700	2010-3-4
Merlin PSA Cable Adapter	EX3170	31700	2010-3-4
Merlin PSA "M" Adapter	EX3180	31700	2010-3-4
Merlin Antenna Adapter	EX3190	31700	2010-3-4
Disposable surgical cable	4051L	47143	2012-2-24
Merlin PSA Patient Cable	EX3150	47143	2010-12-09

Signature:

Kathy Berg
Sr. Manager Regulatory Affairs

June 2020
Issue Date