

Product Highlights

- Torque control and pushability
- Multiple curve options for ease of placement
- Convenient cable alleviates tedious connections
- 1 mm band electrodes

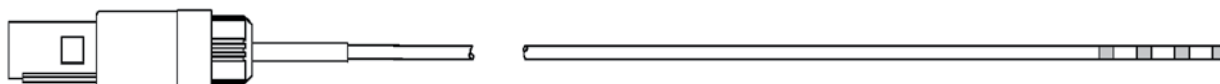
Ordering Information

5 F Quadripolar catheter (1 unit per box)

Reorder Number	French Size	Electrode Spacing (mm)	Curve Type	Usable Length (cm)
401433	5	10	CRD™	120
401859	5	10	CRD-2™	120
401435	5	10	JSN™	120
401441	5	5	CRD™	120
401860	5	5	CRD-2™	120
401443	5	5	JSN™	120
401444	5	5	DAO™	120
401466	5	5	DAO-1™	120
401448	5	2-5-2	CRD™	120
401450	5	2-5-2	JSN™	120
401468	5	2-5-2	DAO-1™	120
401871	5	2	CRD-1™	120

Required Catheter Connecting Cables – Page 124

Reorder Number	Color	Connects these Catheters	Usable Length (cm)
401980	Black	Bipolar and Quadripolar	150
401981	Blue	Bipolar and Quadripolar	150
401982	Grey	Bipolar and Quadripolar	150
401983	Red	Bipolar and Quadripolar	150



Product Highlights

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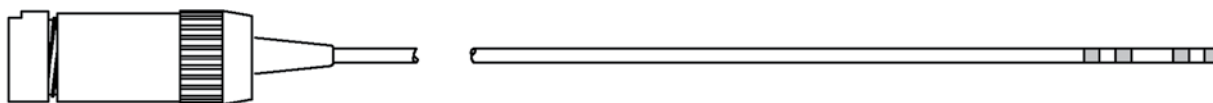
Ordering Information

6 F Quadripolar catheter (1 unit per box)

Reorder Number	French Size	Electrode Spacing (mm)	Curve Type	Usable Length (cm)
401434	6	10	CRD™	120
401436	6	10	JSN™	120
401438	6	10	DAO™	120
401442	6	5	CRD™	120
401474	6	5	CRD-1™	120
402004	6	5	CRD-2™	120
401430	6	5	JSN™	120
401475	6	5	JSN-1™	120
401445	6	5	DAO™	120
401470	6	2	CRD™	120
401449	6	2-5-2	CRD™	120
401451	6	2-5-2	JSN™	120
401453	6	2-5-2	DAO™	120

Required Catheter Connecting Cables – Page 124

Reorder Number	Color	Connects these Catheters	Usable Length (cm)
401980	Black	Bipolar and Quadripolar	150
401981	Blue	Bipolar and Quadripolar	150
401982	Grey	Bipolar and Quadripolar	150
401983	Red	Bipolar and Quadripolar	150



EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 548277**
Issued To: **St. Jude Medical**
14901 DeVeau Place
Minnetonka
Minnesota
55345-2126
USA

In respect of:

Supreme™ Electrophysiology Catheters

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2009-07-01**

Date: **2019-06-25**

Expiry Date: **2024-05-26**

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Page 1 of 6

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 548277

Issued To:

**St. Jude Medical
14901 DeVeau Place
Minnetonka
Minnesota
55345-2126
USA**

Product: Supreme™ Electrophysiology Catheters

Model Number	French Size (F)	Curve Type	Usable Length (cm)	Number of Electrodes	Electrode Spacing (mm)	Tip Electrode Length (mm)	Intended Purpose per IFU	Classification
401430	6F	JSN	120	4	5-5-5	2 mm	St. Jude Medical (SJM) Electrophysiology Catheters can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.	Class III
401433	5F	CRD	120	4	10-10-10	2 mm		Class III
401434	6F	CRD	120	4	10-10-10	2 mm		Class III
401435	5F	JSN	120	4	10-10-10	2 mm		Class III
401436	6F	JSN	120	4	10-10-10	2 mm		Class III
401438	6F	DAO	120	4	10-10-10	2 mm		Class III
401441	5F	CRD	120	4	5-5-5	2 mm		Class III
401442	6F	CRD	120	4	5-5-5	2 mm		Class III
401443	5F	JSN	120	4	5-5-5	2 mm		Class III
401444	5F	DAO	120	4	5-5-5	2 mm		Class III
401445	6F	DAO	120	4	5-5-5	2 mm		Class III
401448	5F	CRD	120	4	2-5-2	2 mm		Class III
401449	6F	CRD	120	4	2-5-2	2 mm		Class III
401450	5F	JSN	120	4	2-5-2	2 mm		Class III
401451	6F	JSN	120	4	2-5-2	2 mm		Class III

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14901 DeVeau Place
Minnetonka
Minnesota
55345-2126
USA**

Model Number	French Size (F)	Curve Type	Usable Length (cm)	Number of Electrodes	Electrode Spacing (mm)	Tip Electrode Length (mm)	Intended Purpose per IFU	Classification
401453	6F	DAO	120	4	2-5-2	2 mm	St. Jude Medical (SJM) Electrophysiology Catheters can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.	Class III
401466	5F	DAO-1	120	4	5-5-5	2 mm		Class III
401468	5F	DAO-1	120	4	2-5-2	2 mm		Class III
401470	6F	CRD	120	4	2-2-2	2 mm		Class III
401474	6F	CRD-1	120	4	5-5-5	2 mm		Class III
401475	6F	JSN-1	120	4	5-5-5	2 mm		Class III
401859	5F	CRD-2	120	4	10-10-10	2 mm		Class III
401860	5F	CRD-2	120	4	5-5-5	2 mm		Class III
401862	5F	JSN	120	10	2-5-2-5-2-5-2-5-2	2 mm		Class III
401863	5F	CSL	120	10	2-8-2-8-2-8-2-8-2	2 mm		Class III
401864	5F	CSL	65	10	2-8-2-8-2-8-2-8-2	2 mm		Class III
401865	5F	CSL	120	10	5-5-5-5-5-5-5-5-5	2 mm		Class III
401871	5F	CRD-1	120	4	2-2-2	2 mm		Class III
401872	5F	CRD-1	120	6	2-2-2-2-2	2 mm		Class III

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Model Number	French Size (F)	Curve Type	Usable Length (cm)	Number of Electrodes	Electrode Spacing (mm)	Tip Electrode Length (mm)	Intended Purpose per IFU	Classification
401876	6F	CRD-1	120	6	5-5-5-175-175	2 mm	St. Jude Medical (SJM) Electrophysiology Catheters can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites	Class III
401877	6F	JSN	120	6	5-5-5-175-175	2 mm		Class III
401878	5F	JSN	120	6	5-5-5-175-175	2 mm		Class III
401890	4F	JSN	120	4	5-5-5	2 mm		Class III
401891	4F	CRD	120	4	5-5-5	2 mm		Class III
401892	4F	DAO	120	4	5-5-5	2 mm		Class III
401893	4F	CSL	65	10	2-8-2-8-2-8-2-8-2	N/A		Class III
401951	6F	JSN	120	4	5-5-5	2 mm		Class III
401952	6F	CRD	120	4	10-10-10	2 mm		Class III
401956	6F	CRD	120	2	10	2 mm		Class III
401957	5F	CRD	120	2	10	2 mm		Class III
401960	5F	JSN	120	5	5-5-5-175	2 mm		Class III
401966	4F	CRD-2	120	6	5-5-5-5-5	2 mm		Class III
401967	4F	CRD-2	120	6	2-2-2-2-2	2 mm		Class III
401968	4F	CRD-2	120	6	2-5-2-5-2	2 mm		Class III

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14901 DeVeau Place
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USA**

Model Number	French Size (F)	Curve Type	Usable Length (cm)	Number of Electrodes	Electrode Spacing (mm)	Tip Electrode Length (mm)	Intended Purpose per IFU	Classification
401969	4F	JSN	120	5	5-5-5-175	2 mm	St. Jude Medical (SJM) Electrophysiology Catheters can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.	Class III
401978	6F	CSL	65	20	2-2	2 mm		Class III
401979	4F	CSL	65	10	2-5-2-5-2-5-2-5-2	N/A		Class III
401993	4F	JSN	120	4	2-2-2	2 mm		Class III
401994	4F	JSN	120	4	2-5-2	2 mm		Class III
401996	4F	CRD	120	4	2-5-2	2 mm		Class III
402003	5F	CRD-2	120	8	2-2-2-2-2-175-175	2 mm		Class III
402004	6F	CRD-2	120	4	5-5-5	2 mm		Class III
402008	5F	CRD-2	120	6	2-5-2-5-2	2 mm		Class III
402009	5F	CRD-2	120	6	5-5-5-5-5	2 mm		Class III
402010	6F	CRD-2	120	6	2-5-2-5-2	2 mm		Class III
402011	6F	CRD-2	120	6	5-5-5-5-5	2 mm		Class III
402012	6F	CRD-2	120	4	5-5-5	2 mm		Class III
402020	6F	CRD	120	20	2-5-2-5-2-5-2-5-2-60-2-10-2-10-2-10-2-10-2	2 mm		Class III
402033	6F	CSL	120	20	5-5-5-5-5-5-5-5-5-42-5-5-5-5-5-5-5-5	2 mm		Class III

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Issued To:

**St. Jude Medical
14901 DeVeau Place
Minnetonka
Minnesota
55345-2126
USA**

Certificate History

Date	Reference Number	Action
01 July 2009	10104508	First issue – Transfer from another Notified Body
30 June 2014	10146394	Certificate Renewal
10 November 2014	10149868	Addition of the St Jude Costa Rica facility as a manufacturing site and of Synergy Health, Costa Rica as a contract sterilizer for the Supreme and Response EP Catheters
25 August 2015	10156926	DuPont Tyvek Medical Transition Project update.
01 February 2016	10160623	Addition of Sterigenics Willowbrook, IL as a sterilizer.
05 December 2016	10165171	Addition of St. Jude Medical Plymouth as a physical manufacturing site.
05 March 2019	7780627	Traceable to NB 0086.
15 April 2019	9718016	Addition of Sterigenics US, LLC, Salt Lake City, Utah for ETO Sterilization
10 June 2019	9767661	Addition of higher capacity sterilization chambers 3 and 4 at Synergy Health Costa Rica and new sterilization process challenge device.
Current	9691014	Certificate Renewal and administrative update to product table format per MDP 4500, Appendix A.

First Issued: **2009-07-01**

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A member of BSI Group of Companies.



ST. JUDE MEDICAL

90131454 Ver K
Declaration of Conformity

SJM Declaration of Conformity

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex II of the Medical Device Directive (MDD) 93/42/EEC as amended by 2007/47/EC. 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
14901 DeVeau Place
Minnetonka, Minnesota 55345-2126 USA

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

Product Type: Electrophysiology Catheter

Product Name(s): Supreme™ Electrophysiology Catheter

Model Number(s): 401430, 401433, 401434, 401435, 401436, 401438, 401441, 401442, 401443, 401444, 401445, 401448, 401449, 401450, 401451, 401453, 401466, 401468, 401470, 401474, 401475, 401859, 401860, 401862, 401863, 401864, 401865, 401871, 401872, 401876, 401877, 401878, 401890, 401891, 401892, 401893, 401951, 401952, 401956, 401957, 401960, 401966, 401967, 401968, 401969, 401978, 401979, 401993, 401994, 401996, 402003, 402004, 402008, 402009, 402010, 402011, 402012, 402020, 402033

Classification: Class III, Rule 7 according to Annex IX of the MDD 93/42/EEC

GMDN Code(s): 46355 Cardiac mapping catheter, percutaneous, single-use

Original CE Mark Date: 01-Jul-2009

Certificate No and expiration date: Certificate No: CE 548277
Expiration Date: 26-May-2024

Applicable Quality System Standards: ISO 13485:2016

Notified Body: BSI Group The Netherlands B.V.
Say Building
John M. Kaynesplein 9
1066 EP Amsterdam
The Netherlands

Signature:


Blair Schwartz
Regulatory Affairs Manager

02 JAN 2020
Issue Date:



SJM Declaration of Conformity

Notified Body Number:

2797 (Traceable to NB number 0086, BSI Reference 7780627)

Manufacturing Facilities:

St. Jude Medical, Costa Rica Ltda.
Edificio #44, Calle 0, Ave. 2
Zona Franca Coyol, El Coyol
Alajuela, Costa Rica

Signature:



Blair Schwartz
Regulatory Affairs Manager

02 Jan 2020
Issue Date:

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Abbott Medical Costa Rica Ltda.
Edificio #44
Calle 0, Ave. 2
Zona Franca Coyol
El Coyol, Alajuela
Costa Rica

Holds Certificate No:

FM 728657

and operates a Quality Management System which complies with the requirements of 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, transeptal access system, introducer catheters, vascular closure systems; and the design of cardiac mapping system accessories.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-05-06

Latest Revision Date: 2022-03-22

Effective Date: 2021-12-14

Expiry Date: 2024-12-13

Page: 1 of 1



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CERTIFICATE



This is to certify that



SANTE
INTERNATIONAL S.A.

SANTE INTERNATIONAL S.A.

Str. Mantuleasa nr. 33, Sector 2
023961 Bucuresti
Romania

has implemented and maintains a **Quality Management System**.

Scope:

Import, trade and storage of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001 : 2015

Certificate registration no. 497269 QM15
Valid from 2021-06-16
Valid until 2024-06-15
Date of certification 2021-06-16



DQS GmbH

Markus Bleher
Managing Director

Accredited Body: DQS GmbH, August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany
Administrative Office: DQS Romania, Str. Brătului nr. 11, 020565 Bucharest - Romania



**Annex to certificate
Registration No. 497269 QM15**

SANTE INTERNATIONAL S.A.

Str. Mantuleasa nr. 33, Sector 2
023961 Bucuresti
Romania

Location

Scope

**075906
Sante International SA
Sos. Mihai Bravu nr. 7, bl. P37-P37A,
sector 2
021303 Bucuresti
Romania**

Import, trade and storage of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices. Consulting for state and private medical units.

**497270
Sante International SA
Str. Pupitrului, nr. 81,
sect. 3
033036 Bucuresti
Romania**

Storage of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.

**31050285
Sante International SA
Calea Ghirodei, nr. 36
300327 Timisoara
Romania**

Trade of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.

**31050284
Sante International SA
Calea Dorobantilor, nr. 111
400609 Cluj-Napoca
Romania**

Trade of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.

**31050283
Sante International SA
Str. Lascar Catargi, nr. 37
700107 Iasi
Romania**

Trade of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.