

FlexAbility™ Ablation Catheter

Product Highlights

- Combines the only flexible tip on the market with a redesigned handle and shaft to accurately navigate within the heart
- Flexible tip conforms to tissue, reducing operator-transmitted force¹
- Up to 70% of flow² directed at the tip-to-tissue interface
- D, F and J curve options
- Symmetric or asymmetric options
- Ergonomic uni- and bi-directional handles are designed for single-handed use and to reduce fatigue

Ordering Information

Contents: 8 F irrigated ablation catheter

| Reorder Number | Description | Curve | French Size | Tip Electrode (mm) | Electrode Spacing (mm) | Length (cm) |
|----------------|--|-------|-------------|--------------------|------------------------|-------------|
| A701124 | Bi-D Irrigated Ablation Catheter (4-hole) | D-D | 8 | 4 | 1-4-1 | 115 |
| A701125 | Bi-D Irrigated Ablation Catheter (4-hole) | D-F | 8 | 4 | 1-4-1 | 115 |
| A701127 | Bi-D Irrigated Ablation Catheter (4-hole) | F-F | 8 | 4 | 1-4-1 | 115 |
| A701128 | Bi-D Irrigated Ablation Catheter (4-hole) | F-J | 8 | 4 | 1-4-1 | 115 |
| A701129 | Bi-D Irrigated Ablation Catheter (4-hole) | J-J | 8 | 4 | 1-4-1 | 115 |
| A701157 | Uni-D Irrigated Ablation Catheter (4-hole) | D | 8 | 4 | 1-4-1 | 115 |
| A701158 | Uni-D Irrigated Ablation Catheter (4-hole) | F | 8 | 4 | 1-4-1 | 115 |
| A701159 | Uni-D Irrigated Ablation Catheter (4-hole) | J | 8 | 4 | 1-4-1 | 115 |

Required Catheter Connecting Cable: Model 1641



¹Report 90042968, on file

²Report 90058001, on file

ID-2001424 A EN (08/14)

EC Design-Examination Certificate

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

No. **CE 616451**
Issued To: **St. Jude Medical**
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

In respect of:

FlexAbility Ablation 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: **2014-07-11**

Date: **2019-07-10**

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

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Page 1 of 4

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 616451

Issued To:

**St. Jude Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA**

FlexAbility Ablation Catheters - Model Numbers

| Handle Type | Curve Shape | Model Number |
|-----------------|-------------|--------------|
| Bi-Directional | D-D | A701124 |
| Bi-Directional | D-F | A701125 |
| Bi-Directional | F-F | A701127 |
| Bi-Directional | F-J | A701128 |
| Bi-Directional | J-J | A701129 |
| Uni-Directional | D | A701157 |
| Uni-Directional | F | A701158 |
| Uni-Directional | J | A701159 |

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5050 Nathan Lane North
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55442
USA**

FlexAbility Ablation Catheters, Sensor Enabled - Model Numbers

| Handle Type | Curve Shape | Model Number |
|-----------------|-------------|--------------|
| Bi-Directional | D-D | A-FASE-DD |
| Bi-Directional | D-F | A-FASE-DF |
| Bi-Directional | F-F | A-FASE-FF |
| Bi-Directional | F-J | A-FASE-FJ |
| Bi-Directional | J-J | A-FASE-JJ |
| Uni-Directional | D | A-FASE-D |
| Uni-Directional | F | A-FASE-F |
| Uni-Directional | J | A-FASE-J |

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55442
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Certificate History

| Date | Reference Number | Action |
|------------------|------------------|---|
| 11 July 2014 | 10149399 | First Issue. |
| 10 June 2015 | 10156225 | Tip shaft buckle force product specification change. |
| 25 August 2015 | 10156926 | DuPont Tyvek Medical Transition Project update. |
| 03 December 2015 | 10158976 | Addition of FlexAbility Ablation Catheter Sensor Enabled model numbers. Update to the Instructions for Use for the existing FlexAbility Ablation Catheters to expand the use in epicardial procedures. |
| 01 February 2016 | 10160623 | Addition of Sterigenics Willowbrook, IL as a sterilizer. |
| 13 July 2017 | 10171416 | IFU clarification for the epicardial use on patient with ventricular tachycardia. Shelf life extension to 3 years and addition of Costa Rica manufacturing facility and sterilization site for FlexAbility Ablation Catheter, Sensor Enabled. |
| 05 March 2019 | 8250541 | Traceable to NB 0086. |
| 10 April 2019 | 9752188 | Addition of Sterigenics US, LLC, Salt Lake City, Utah for ETO Sterilization. |
| 26 June 2019 | 9767562 | Addition of higher capacity sterilization chambers 3 and 4 at Synergy Health Costa Rica and new sterilization process challenge device. |
| Current | 9690853 | Certificate Renewal. |

First Issued: **2014-07-11**

Date: **2019-07-10**

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

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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.

SJM Declaration of Conformity FlexAbility Product Family

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. 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
5050 Nathan Lane N
Plymouth, MN 55442, USA

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

Product Type: Ablation Catheter

Product Name(s): FlexAbility Ablation Catheter
FlexAbility Ablation Catheter, Sensor Enabled

Model Number(s): A701124, A701125, A701127, A701128, A701129,
A701157, A701158, A701159
A-FASE-DD, A-FASE-DF, A-FASE-FF, A-FASE-FJ, A-
FASE-JJ, A-FASE-D, A-FASE-F, A-FASE-J

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

GMDN Code(s): 61785

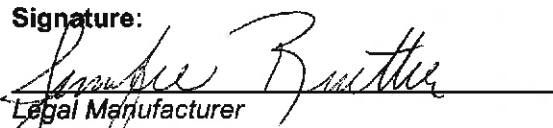
Original CE Mark Date: 11 July 2014

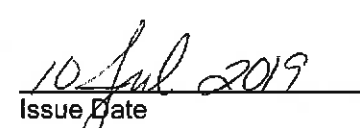
Certificate No and expiration date: Certificate No: CE 616451
Expiration Date: 26 May 2024

Applicable Quality System Standards: EN ISO 13485:2016

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

Notified Body Number: 2797
Traceable to NB number 0086, BSI Reference 8250541

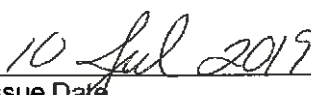
Signature: 
Legal Manufacturer
Jennifer Ruether
Regulatory Affairs Manager

Issue Date: 
10 Jul 2019

SJM Declaration of Conformity FlexAbility Product Family**Manufacturing Facilities:**

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

Signature:

Legal Manufacturer
Jennifer Ruether
Regulatory Affairs Manager

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

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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. Buzului 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.

