# 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 force[1]
- Up to 70% of flow[2] 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


[1]Report 90042968, on file
[2]Report 90058001, on file

Digitally signed by Ceaicovschi Tudor
Date: 2023.09.28 13:22:34 EEST
Reason: MoldSign Signature
Location: Moldova



ID-2001424 A EN (08/14)

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# 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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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 |

First Issued: **2014-07-11** Date: **2019-07-10** Expiry Date: **2024-05-26**

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**Plymouth**
**Minnesota**
**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 |

First Issued: **2014-07-11** Date: **2019-07-10** Expiry Date: **2024-05-26**

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**USA**

# 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 FlexAbiliy 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<br>5050 Nathan Lane N<br>Plymouth, MN 55442, USA |
| **European Representative:** | St. Jude Medical Coordination Center BVBA<br>The Corporate Village<br>Da Vincilaan 11 Box F1<br>1935 Zaventem, Belgium |
| **Product Type:** | Ablation Catheter |
| **Product Name(s):** | FlexAbility Ablation Catheter<br>FlexAbility Ablation Catheter, Sensor Enabled |
| **Model Number(s):** | A701124, A701125, A701127, A701128, A701129, A701157, A701158, A701159<br>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<br>Expiration Date: 26 May 2024 |
| **Applicable Quality System Standards:** | EN ISO 13485:2016 |
| **Notified Body:** | BSI Group The Netherlands B.V.<br>Say Building<br>John M. Kaynesplein 9<br>1066 EP Amsterdam<br>The Netherlands |
| **Notified Body Number:** | 2797<br>Traceable to NB number 0086, BSI Reference 8250541 |

**Signature:**

*Legal Manufacturer*
*Jennifer Ruether*
*Regulatory Affairs Manager*

10 Jul 2019
Issue Date



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# SJM Declaration of Conformity FlexAbility Product Family

**Manufacturing Facilities:**

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

**Signature:**

Jennifer Ruether

*Legal Manufacturer*
*Jennifer Ruether*
*Regulatory Affairs Manager*

10 Jul 2019
Issue Date



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By Royal Charter

# 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, transseptal 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
Effective Date: 2021-12-14
Latest Revision Date: 2022-03-22
Expiry Date: 2024-12-13



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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

# CERTIFICATE

This is to certify that

## 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. Bucatului 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**<br>**Sante International SA**<br>**Sos. Mihai Bravu nr. 7, bl. P37-P37A, sector 2**<br>**021303 Bucuresti**<br>**Romania** | Import, trade and storage of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices. Consulting for state and private medical units. |
| **497270**<br>**Sante International SA**<br>**Str. Pupitrului, nr. 81, sect. 3**<br>**033036 Bucuresti**<br>**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**<br>**Sante International SA**<br>**Calea Ghirodei, nr. 36**<br>**300327 Timisoara**<br>**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**<br>**Sante International SA**<br>**Calea Dorobantilor, nr. 111**<br>**400609 Cluj-Napoca**<br>**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**<br>**Sante International SA**<br>**Str. Lascar Catargi, nr. 37**<br>**700107 Iasi**<br>**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. |

This annex (edition:2021-06-16 ) is only valid in connection with the above-mentioned certificate.