

## 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<sup>1</sup>
- Up to 70% of flow<sup>2</sup> 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



<sup>1</sup>Report 90042968, on file

<sup>2</sup>Report 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

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

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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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# EC Design-Examination Certificate

## Supplementary Information to CE 616451

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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 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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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

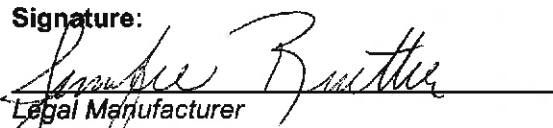
**Original CE Mark Date:** 11 July 2014

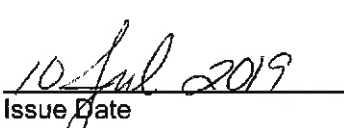
**Certificate No and expiration date:** Certificate No: CE 616451  
Expiration Date: 26 May 2024

**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

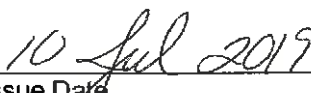
**Notified Body Number:** 2797  
Traceable to NB number 0086, BSI Reference 8250541

**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



**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.