

Product Highlights

Improve stability with redesigned smaller patches.¹

- Improved adhesive hydrogel patches.¹
- Improves ECG patch placement options.
- New singular patch kit with minimal size to accommodate patients of all sizes.

Ordering Information

Reorder Number	Description
EN0020-P	EnSite Precision™ Surface Electrode Kit



¹ St. Jude Medical. Data on File. Report 90213771.

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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SJM Declaration of Conformity EnSite Precision™ Surface Electrode Kit

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex VII 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 Costa Rica Ltda. Edificio #44, Calle 0, Ave. 2, Zona Franca, El Coyol Alajuela Costa Rica
European Representative:	St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
Product Type:	Cardiac Mapping and Medical Positioning System Accessories
Product Name(s):	EnSite Precision™ Surface Electrode Kit
Model Number(s):	EN0020-P
Classification:	Class I, Rule 1, according to Annex IX of the MDD
GMDN Code(s):	46007 - Cardiac Mapping System Reference Patch
Original CE Mark Date:	21 January 2016
Certificate No and expiration date:	Certificate No: MD 639058 Expiration Date: 13 December 2021
Applicable Quality System Standards:	ISO 13485:2016 & EN ISO 13485:2016
Notified Body:	N/A
Notified Body Number:	N/A

Signature:



Jack Kfomenhoek
Associate Director, Regulatory Affairs

05-MAR-2019

Issue Date

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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. Bratului 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.