

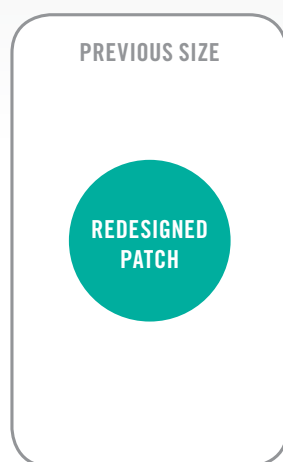
## Product Highlights

Improve stability with redesigned smaller patches.<sup>1</sup>

- Improved adhesive hydrogel patches.<sup>1</sup>
- 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



<sup>1</sup> St. Jude Medical. Data on File. Report 90213771.

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

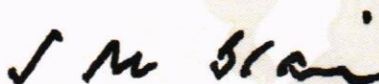
St. Jude Medical Costa Rica Ltda.  
Edificio #44, Calle 0, Ave. 2, Zona  
Franca, El Coyo  
ALAJUELA  
Costa Rica

Holds Certificate Number:

**MD 639058**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, Manufacture and distribution of radio-frequency (RF) ablation catheters, electrophysiology (EP) catheters, intracardiac echocardiography catheters, cardiac mapping and medical positioning system accessories, transseptal access system, introducer catheters, diagnostic guidewire, vascular closure systems, sterile imaging catheters and the distribution of syringes, sterile bags and accessories.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2015-08-19

Latest Revision Date: 2019-02-26

Effective Date: 2019-02-26

Expiry Date: 2021-12-13

Page: 1 of 2



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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.

Certificate No:

**MD 639058**

Location

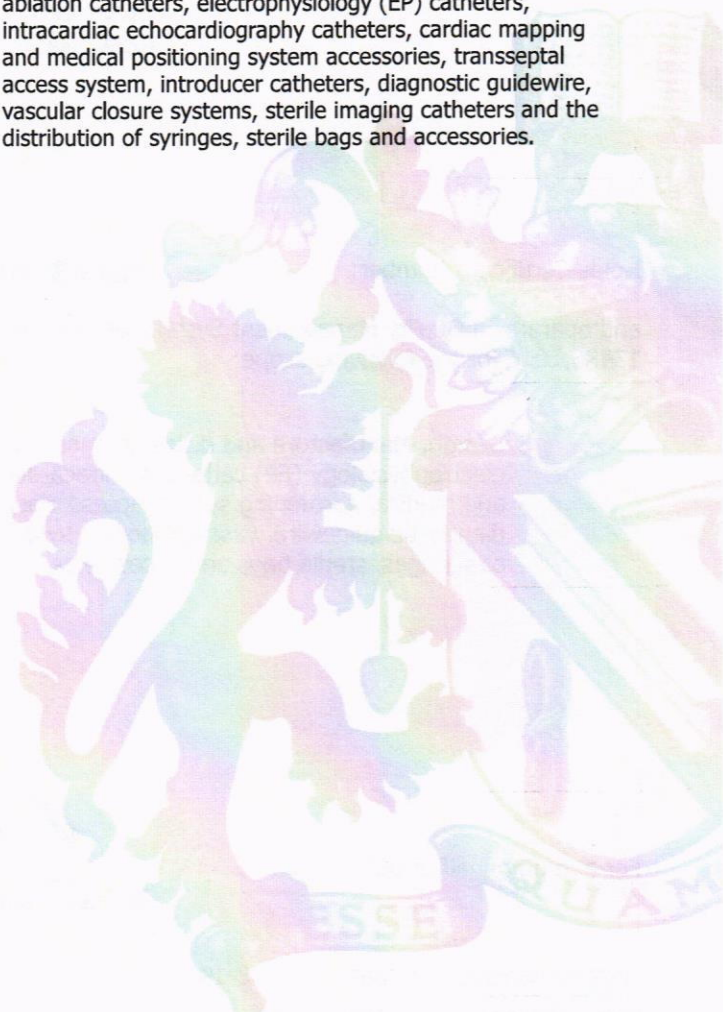
Registered Activities

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

Design, Manufacture and distribution of radio-frequency (RF) ablation catheters, electrophysiology (EP) catheters, intracardiac echocardiography catheters, cardiac mapping and medical positioning system accessories, transeptal access system, introducer catheters, diagnostic guidewire, vascular closure systems, sterile imaging catheters and the distribution of syringes, sterile bags and accessories.

Abbott  
Edificio 44, Calle 0, Avenida 2  
Zona Franca El Coyol  
El Coyol  
Alajuela  
Costa Rica

Design, Manufacture and distribution of radio-frequency (RF) ablation catheters, electrophysiology (EP) catheters, intracardiac echocardiography catheters, cardiac mapping and medical positioning system accessories, transeptal access system, introducer catheters, diagnostic guidewire, vascular closure systems, sterile imaging catheters and the distribution of syringes, sterile bags and accessories.



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ST. JUDE MEDICAL

90221217 Rev. G


Declaration of Conformity

## 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).

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

Signature:

  
Jack Kfomenhoek  
Associate Director, Regulatory Affairs

05-MAR-2019  
Issue Date