EnSite Precision™ Surface Electrode Kit

Mapping & Visualization

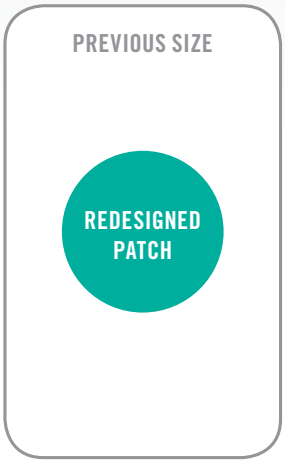
Product Highlights

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.

SJM-CAG-0915-0035(1) | Item approved for international use only.

ST. JUDE MEDICAL

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 Coyol
El Coyol, 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:

Manufacture and distribution of radio-frequency (RF) ablation catheters, electrophysiology (EP) catheters, intracardiac echocardiography catheters, cardiac mapping system accessories, transseptal access system, introducer catheters, diagnostic guidewire, vascular closure systems, and the design of cardiac mapping system accessories.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2015-08-19
Effective Date: 2021-12-14
Latest Revision Date: 2021-11-25
Expiry Date: 2022-06-13

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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
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, diagnostic guidewire, vascular closure systems; and the design of cardiac mapping system accessories.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-05-06
Effective Date: 2021-12-14
Latest Revision Date: 2021-12-06
Expiry Date: 2022-06-13

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90603860 Rev. D

MDR Declaration of Conformity

Manufacturer:	St. Jude Medical Costa Rica Ltda
Manufacturer SRN:	TBD
Address:	Edificio #44 Calle 0, Ave. 2 Zona Franca Coyol El Coyol, Alajuela Costa Rica
Manufacturing Site(s):	St. Jude Medical Costa Rica Ltda Edificio #44 Calle 0, Ave. 2 Zona Franca Coyol El Coyol, Alajuela Costa Rica
European Authorized Representative:	Abbott Medical The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Product Type:	Surface Electrodes
Product Trade Name(s):	See products list below.
Model Number(s):	See products list below.
Intended Purpose:	Transmit information from the patient to the EnSite Precision™ Cardiac Mapping System for signal conditioning and data inference.
Risk Classification:	Class I
Classification Rationale:	Medical Device Regulation 2017/745, Annex VIII, Rule 13
EMDN Code(s):	Z12059002, Cardiac Mapping Equipment
Basic UDI-DI:	5414734DMS0040HX

Signature: Lauren Eno Manager, Regulatory Affairs	21 Jul 2021 Issue Date On behalf of Abbott Medical, signed at St. Paul, MN

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90603860 Rev. D

MDR Declaration of Conformity

The products described in this declaration are in conformity with all applicable EU harmonized legislation, including:

- Regulation (EU) 2017/745, and the applicable *General Safety & Performance Requirements* in Annex 1
- Directive 2011/65/EU
- Directive (EU) 2015/863
- Directive 2006/42/EC on Machinery and Directive 89/686/EEC (and the superseding Regulation (EU) 2016/425) on Personal Protective Equipment do not apply

Common Specifications / Standards Applied:	N/A
STED #	90602432
Notified Body:	N/A
Supporting Certificate(s):	EC Certificate No: N/A Expiration Date: N/A QMS Certificate No: MD 639058 and FM 728657 Expiration Date: 2021-12-13
Original CE Mark Date:	18 March 2020
Conformity Assessment:	Annex II and Annex III
Device Photograph:	N/A

The products in the attached Declaration of Conformity Product List are CE Marked.

Declaration of Conformity Product List

Model No.	Description	UDI DI
SURF-ELEC-2PRS	EnSite Locating Electrodes	05415067032300
SYS-REF-V1	EnSite System Reference Electrode	05415067031402
PRCN-SEK-A	EnSite Precision Surface Electrode Kit	05415067032355

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