



Abbott Medical Costa Rica Ltda.
 Edificio #44
 Calle 0, Ave 2
 Zona Franca Coyol
 El Coyol, Alajuela Costa Rica
 Tel: 1 855 478 5833
 Fax: 1 651 756 5833

0091621 Rev. B

MDR Declaration of Conformity

Manufacturer:	Abbott 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):	Abbott 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
European Authorized Representative SRN:	BE-AR-000008744

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

Product Trade Name(s):	EnSite™ X EP System Surface Electrode Kit
Model Number(s):	ENSITE-SEK-5-I-01
Intended Purpose:	The EnSite™ X EP System Surface Electrode Kit is used to transmit information from the patient to the EnSite™ X EP 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):	Z120590, Various Instruments for Cardiology and Cardiac Surgery
Basic UDI-DI:	5414734DMS0041HZ

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

Signature:  _____ Manager, Regulatory Affairs	21 April 2023 _____ Issue Date On behalf of Abbott Medical, signed at St. Paul, MN
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- Regulation (EU) 2017/745, and the applicable *General Safety & Performance Requirements* in Annex 1
- Regulation (EU) 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
Notified Body:	N/A
Supporting Certificate(s):	Technical Documentation Assessment Certificate Number: N/A EU Quality Management System Certificate: MD 728658
Original CE Mark Date:	22 May 2020
Conformity Assessment:	Annex II and Annex III