

Article 22 – Procedure Pack MDR Statement of Conformity

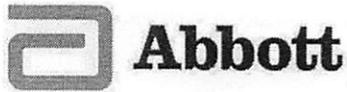
This statement is issued under the sole responsibility of the Procedure Pack Assembler.

In Accordance with Article 22, Section 2 of Regulation (EU) 2017/745, Abbott Medical Costa Rica, Ltda.:

- has verified the, mutual compatibility of the devices in accordance with the manufacturers' instructions and has carried out his operations in accordance with these instructions; and
- has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers; and
- the activity of combining device and, if applicable, other products as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.

| Procedure Pack Assembler | | European Authorized Representative |
|---|--|--|
| Abbott Medical Costa Rica Ltda. Edificio #44 Calle 0, Ave. 2 Zona Franca Coyol El Coyol, Alajuela Costa Rica | | Abbott Medical The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium |
| SRN: TBD | | SRN: BE-AR-000008744 |
| Model Number: | EN0020-P | |
| Product Trade Name: | EnSite Precision™ Surface Electrode Kit | |
| Intended Purpose: | The EnSite Precision™ Surface Electrode Kit is used to transmit information from the patient to the EnSite Precision™ Cardiac Mapping System for signal conditioning and data inference. | |
| Basic UDI: | UDI-DI: | EMDN: |
| 5414734DMS0039JE | 05415067041715 | Z120590, Various Instruments for Cardiology and Cardiac Surgery |
| Supporting Certificates: | QMS Certificate No: MD 728658, EN ISO 13485:2016 | |
| Risk Class: | See Device Table Below | |

| | |
|--|--|
| Signature:  _____ Monica Pimay Manager, Regulatory Affairs | 11 Aug 2023 _____ Issue Date On behalf of Abbott Medical, signed at St Paul, MN |
|--|--|



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| Device Table (Procedure Pack contains the following devices) | | | | | | |
|--|----------------|---------|--|-----------------------|--|----------------|
| Device Name | Model Number | Class | Manufacturer | Conformity Assessment | Technical Documentation Assessment Certificate | UDI-DI |
| EnSite™ Locating Electrodes | SURF-ELEC-2PRS | Class 1 | Abbott Medical Costa Rica Ltda. Edificio #44 Calle 0, Ave. 2 Zona Franca Coyoil El Coyoil, Alajuela Costa Rica | Annex II and III | N/A | 05415067032300 |
| EnSite™ System Reference Electrode | SYS-REF-V1 | Class 1 | Abbott Medical Costa Rica Ltda. Edificio #44 Calle 0, Ave. 2 Zona Franca Coyoil El Coyoil, Alajuela Costa Rica | Annex II and III | N/A | 05415067031402 |
| 3M™ Red Dot™ Electrodes | 2570-5 | Class 1 | 3M Health Care 2510 Conway Avenue St. Paul, MN 55144-10000 USA | Annex II and III | N/A | 10707387789333 |

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