RED Declaration of Conformity

Abbott Medical hereby declares that the following product(s) conform to the applicable provisions of the Radio Equipment Directive (2014/53/EU). All supporting documentation is retained under the premises of Abbott Medical. 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:	Abbott Medical One St. Jude Medical Drive St. Paul, Minnesota 55117-9913 US
European Representative:	Abbott Medical The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
Product Type:	Electrophysiology Mapping System Hardware
Applicable Standards:	EN 301 489-1 V2.2.3 (2019-11) EN 301 489-3 V2.3.2 (2023-01) IEC 60601-1:2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 IEC 60601-1-2:2014 + AMD1:2020 EN 303 454 V1.1.1 (2018-01)
Applicable Annex:	Annex III
Notified Body:	Element Materials Technology Portland-Evergreen Inc. 6775 NE Evergreen Parkway, Suite 400 Hillsboro, OR 97124 Country: United States
Notified Body Number:	0981
Technical Construction File:	90591882

Signature:

REICHDK

Digitally signed by REICHDK
Date: 2024.07.11 11:24:02 -05'00'

Daniel Reichert
Sr. Manager Design Assurance

Issue Date

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Product Name (s)	Model #	Description of accessories and components:
EnSite™ X EP System Amplifier	ENSITE-AMP-02 ENSITE-R-AMP-02 ENSITE-AMP-01 ENSITE-R-AMP-01	
EnSite™ X EP System Amplifier Power Module	ENSITE-AMP-EPM-01	
EnSite™ X EP System Field Frame	ENSITE-FF-01 ENSITE-R-FF-01	
EnSite™ X EP System Field Frame Cable	ENSITE-FF-3MC-01	
EnSite™ X EP System Field Frame Cable	ENSITE-FF-4.5C-01	
EnSite™ X EP System Patient Reference Sensor 3	ENSITE-PRSBACK-01	
EnSite™ X EP System Patient Reference Sensor 1	ENSITE-PRSFRNT-01	