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, 15900 Valley View Court, Sylmar, CA 91342, USA
European Representative	Abbott Medical, The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, BELGIUM
Product Type:	Implantable Monitoring and Recording Device
Applicable Standards:	3.1a: EN50663:2017, SAR: 1999/519/EC EN45502-1:2015, ISO14708-1:2014, EN45502-2-1:2003, ISO 14708-2:2019 ISO14117:2019 3.1b: EN 45502-2-1:2003, ISO 14117:2019, IEC 60601-1-2:2014 + A1:2020, EN 301 489-1 V2.2.3:(2019-11), EN 301 489-17 V3.2.4:(2020-09) 3.2: EN 300 328 V2.2.2 (2019-07)
Applicable Annex:	III
Technical Construction File:	90989913

Signature:

Umesh

Umesh Shah,
Director Software Quality

May 15, 2024
Issue Date

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Product Name (s)	Model #	Description of accessories and components:
Assert-IQ™	DM5000, DM5300 and DM5500	The Assert-IQ™ ICM is intended to help physicians and clinicians monitor, diagnose and document the heart rhythm in patients who are susceptible to cardiac arrhythmias and unexplained symptoms by detecting arrhythmias and transmitting data for review.