

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) and subsequent supplements 2017/1354, 2019/320, and 2022/30. 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, 6901 Preston Road, Plano, Texas 75024
USA

European Representative Abbott Medical, The Corporate Village, Da Vincilaan 11
Box F1, 1935 Zaventem, Belgium

Product Type: Implantable Neurostimulator Charger

Applicable Standards: *Article 3.1(a): Health and Safety*
EN 62479:2010,
EN IEC 60601-1:2005+A1:2012,
EN IEC 60601-1-2:2014+A1:2020,
EN IEC 60601-1-11:2015+A1:2020

3.1(b): EMC
EN 301 489-1 V2.2.3,
EN 301 489-17 V3.2.4

3.2: Efficient use of the spectrum
EN 300 328 V2.2.2

Applicable Annex: Annex II

Technical Construction File: 90979265

Signature:



Dan Gilbert
Director, Development Quality Engineering
Plano, TX 75024

03 APR 2026
Issue Date

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Product Name (s)	Model #	Description of accessories and components:
Charger	16000	• None

Signature:

Dan Gilbert
Director, Development Quality Engineering
Plano, TX 75024

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Issue Date