

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, 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 with Wireless Charger
Applicable Standards:	3.1a: BS EN 62479:2010, BS EN 62366-1:2015+A1:2020, BS EN 50566:2017, BS EN IEC 62311:2020, BS EN IEC 62311:2020 IPG: ISO 14708-1: 2014, ISO 14708-3: 2017, BS EN 45502-1: 2015 Charger only: BS EN 60601-1-2:2015/A1:2021 BS EN 60601-1-11:2015+A1:2021 BS EN 60601-1-6:2010+A2:2021 3.1b: ETSI EN 301 489-1 V2.2.3, ETSI EN 301 489-17 V3.2.4 Charger only: ETSI EN 301 489-31 V2.1.1 3.2: ETSI EN 300 328 V2.2.2, ETSI EN 300 330 V2.1.1 (partial), ETSI EN 303 417 V1.1.1 (partial)
Applicable Annex:	Annex II, IPG and Charger Annex IV, Charger
Technical Construction File:	90979265



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Signature:

Christopher Longpre
Director, Development Quality Engineering
Plano, TX 75024

06 Sept 2023

Issue Date

Product Name (s)	Model #	Description of accessories and components:
Eterna™ SCS IPG	32400	• None
Charger	16000	• None