

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 St. Jude Medical Coordination Center BVBA,

The Corporate Village, Da Vincilaan 11 Box F1,

1935 Zaventem, Belgium

Product Type: Implantable Neurostimulator

Applicable Standards: 3.1a:

BS EN 62479:2010

IEC 62366-1:2015+AMD 1:2020

BS EN 50566:2017 IEC 62311: 2019 BS EN IEC 62311:2020 ISO 14708-1: 2014 ISO 14708-3: 2017 EN 45502-1: 2015

3.1b:

ETSI EN 301 489-1 V2.2.3 ETSI EN 301 489-17 V3.2.4

3.2:

ETSI EN 300 328 V2.2.2

Applicable Annex: Annex II

Technical Construction File: 90979265

Signature:

Director, Development Quality Engineering

Plano, TX 75024

Z4JAN 2025 Issue Date



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| Product Name (s) | Model # | Description of accessories and components: |
|---------------------|---------|--|
| Liberta RC™ DBS IPG | 62400 | • None |