Abbott Declaration of Conformity [IonicRF™ Generator]

Abbott Medical (Abbott) hereby declares that the following Abbott facilities and products conform to the applicable provisions of Annex II of the Medical Device Directive (MDD) 93/42/EEC as amended by 2007/47/EC. All supporting documentation is retained under the premises of Abbott. We declare no application has been lodged with any other notified body for the same products. 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 5050 Nathan Lane North Plymouth, Minnesota 55442, USA
European Representative:	Abbott Medical The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
Product Type:	Radiofrequency Generator
Product Name(s):	IonicRF™ Generator
Model Number(s):	RFG-IONIC
Classification:	Class IIb Medical Device Directive 93/42/EEC, Annex IX, Rule 9
GMDN Code(s):	35156 – Radiofrequency Ablation System Generator
Original CE Mark Date:	31 May 2020
Certificate No and expiration date:	Certificate No: CE 701333 Expiration Date: 15 May 2023
Applicable Quality System Standards:	ISO 13485:2016
Notified Body:	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Netherlands
Notified Body Number:	2797
Manufacturing Facilities:	St. Jude Medical One St. Jude Medical Drive St. Paul, Minnesota 55442, USA

Signature:

Jennifer Wong
Sr Director, Regulatory Affairs

10 Dec 2020
Issue Date