Staefa (Switzerland), September 2020 / G. Borrett, Senior Manager Regulatory Affairs

Declaration of Conformity

Hearing Instrument System Accessories

Easy Line Remote	v1	Easy Line Remote	v2
myPhonak	v3	myPhonak	v4
Phonak Remote	v2	Unitron Remote Plus	v3
Selectic Remote	v2	Hearing Remote	v3
HANSATON stream remote app	v2		

We, Sonova AG, Laubisrütistrasse 28, 8712 Stäfa, hereby declare under our own responsibility that the medical device Class IIa mentioned above, is in conformity with essential requirements of the Medical Device Directive 93/42/EEC (MDD).

This product is in conformity with the following standards and/or other normative documents:

EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971	Medical devices - Application of risk management to medical devices
EN 62304	Medical Device Software - Lifecycle Management
EN 62366	Medical Device Software - Usability Engineering

Additional Information:

This declaration is supported by	Certificate of approval No.32433 to quality standard ISO 13485:2016 issued by LNE/G-Med and EC Certificate No:32438 acc. To ANNEX II excl #4 DIRECTIVE 93/42/EEC issued by LNE/G-Med
Technical File held by	Sonova AG, Laubisrütistrasse 28 CH-8712 Stäfa, Switzerland
GMDN code	60211

Staefa, 14 September 2020

Laurent Vicari
Director Quality Management & Regulatory Affairs

Staefa, 14 September 2020

Glenn Borrett
Senior Manager Regulatory Affairs

GMED (0459) reconnait que son certificat CE est valide pour les dispositifs médicaux décrits le 24 septembre 2020

GMED (0459) recognizes that its EC certificate is valid for the medical devices listed September 24, 2020

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