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

Declaration of Conformity

Hearing Instrument System Accessories

Easy Line Remote	V1.X *		Easy Line Remote	V2.X
myPhonak	3.X		myPhonak	4.X
Phonak Remote	V 2.X		Unitron Remote Plus	V3.X
Selectic Remote	V2.X		Hearing Remote	V3.X
HANSATON stream remote app	V2.X			

*X Denotes minor SW version

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, 27 August 2020

Andi Vonlanthen
GVP Research & Development

Staefa, 27 August 2020

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