GMED (0459) reconnait que son certificat CE est valide pour les dispositifs médicaux décrits
J. SECRESNIAK
GMED (0459) recognizes that its EC certificate is valid for the medical devices listed

12 AOUT 2019

sonova
HEAR THE WORLD

Staefa (Switzerland), July 2019 / G. Borrett, Manager Regulatory Affairs

Declaration of Conformity

Hearing Instrument System Accessories

Easy Line Remote V1.0
Phonak Remote V 2.1
Selectic Remote V2.0
HANSATON stream remote app
myPhonak 3.0
Unitron Remote Plus
Hearing Remote

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/ECC (MDD).

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

ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
ISO 14971	Medical devices - Application of risk management to medical devices
IEC 62304	Medical Device Software - Lifecycle Management
IEC 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 (former 61475)

Staefa, 15 July 2019

L. Vicari
Director Director Quality Management & Regulatory Affairs

Staefa, 15 July 2019

D. Popov
Director Corporate Manufacturing Engineering

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