sonova
HEAR THE WORLD

Declaration of Conformity

ID: 000.000.025.352, V2.0

Hearing Instrument System Accessory

Roger 21 (02)

We, Sonova AG, Laubisrütistrasse 28, 8712 Stäfa, Switzerland, hereby declare under our sole responsibility that the medical device Class I mentioned above, is in conformity with essential requirements of the Medical Device Directive 93/42/ECC (MDD) Annex I and with the Radio Equipment Directive 2014/53/EU and following standards:

Requirement	Standard
HEALTH & SAFETY (Art. 3(1)(a))	IEC 60601-1: 2005 + Corr.1: 2006 + A1:2012 EN 60601-1: 2006 + A11: 2011 + A1:2013 UNE-EN 60601-1: 2008 + Erratum 2008 + Corr.: 2010 + A11: 2012
EMC (Art. 3(1)(b))	ETSI EN 301 489-1 V1.9.2 (2011) ETSI EN 301 489-3 V1.6.1 (2013) EN 60601-1-2:2015 ; IEC 60601-1-2:2014
RADIO SPECTRUM (Art. 3(2))	ETSI EN 300 440-1 V1.6.1 (2010) ETSI EN 300 440-2 V1.4.1 (2010)

Additional Information:

This declaration is supported by	Certificate of approval No. 32432 to quality standard ISO 9001:2008 and No. 32433 to quality standard ISO 13485:2003 issued by LNE/G-Med
Technical File is held by	Sonova AG Laubisrütistrasse 28 CH-8712 Stäfa, Switzerland
GMDN code	57961

Signed on behalf of Sonova AG

Stäfa, June 12, 2017

H. Mehl
Group Vice President
Operations

Stäfa, June 12, 2017

A. Vonlanthen
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