PHONAK
life is on

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Declaration of Conformity

ID: 000.000.015.079, V6.0

Hearing Instrument System Accessories:

Phonak PilotOne II
Phonak PilotOne II (Selectic)

We, Phonak 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+Cor.1:2006+Cor.2:2007+A1:2012; EN 60601-1 :2006+Cor.2:2007+A1:2012 IEC 60950-1 :2005 2ed.+A1:2009+A2:2013 and EN 60950-1 :2006+A11:2009+A1:2010+A2:2013 AC:2011+A12:2011 IEC 62479 :2010
EMC (Art. 3(1)(b))	ETSI EN 301 489-1 V1.9.2 (2011) ETSI EN 301 489-3 V1.6.1 (2013) EN 60601-1-2:2007+Cor:2010
RADIO SPECTRUM (Art. 3(2))	ETSI EN 300 330-1 V1.8.1 (2015); ETSI EN 300 330-2 V1.6.1 (2015) ETSI EN 300330 V2.1.1 (2017)

Additional Information:

This declaration is supported by	Certificate of approval No. 31857 to quality standard ISO 9001:2008 and No.30379 to quality standard ISO 13485:2003 issued by LNE/G-Med
Technical File is held by	Phonak AG, Laubisrütistrasse 28 CH-8712 Stäfa, Switzerland
GMDN Code	57885

Signed on behalf of Phonak AG

Stäfa, June 12, 2017

H. Mehl
Group Vice President
Operations

Stäfa, June 12, 2017

J. Itin
Director of Corporate TQM & RA