

Declaration of Conformity

ID: 000.000.015.568, V4.0

Hearing Instrument System Accessory: Phonak ComPilot Air II

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; EN 60601-1 :2006+Cor.2010 IEC 60950-1 :2005 (2nd Ed.)+A1:2009+A2:2013 EN 60950-1 :2006+A11:2009+A1:2010+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) ETSI EN 301 489-17 V2.2.1 (2012) 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) ETSI EN 300328 V1.9.1 (2015) ETSI EN 300328 V2.1.1 (2016)

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	57886

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