

RED Declaration of Conformity

We, Sonova AG, Laubisrütistrasse 28, 8712 Stäfa, Switzerland, hereby declare under our sole responsibility that the radio equipment (wireless hearing aids) listed on page 2, to which this declaration relates, is in conformity with the Radio Equipment Directive 2014/53/EU and following standards:

Requirement	Standard
HEALTH & SAFETY (Art. 3(1)(a))	EN/IEC 60601-1 :2006 EN/IEC 62479 :2010
EMC (Art. 3(1)(b))	EN 60601-1-2:2015 EN 301 489-1 V 2.2.0 EN 301 489-17 V 3.2.0 EN/IEC 60601-1-2 ed.4
RADIO SPECTRUM (Art. 3(2))	EN 300 328 V2.1.1

Additional Information:

This declaration is supported by	Certificate of approval No.32433 to quality standard ISO 13485:2016 issued by G-Med
Technical File is held by	Sonova AG, Laubisrütistrasse 28 CH-8712 Stäfa, Switzerland

Stäfa, 31 March 2021



Laurent Vicari
Director Quality Management & Regulatory
Affairs

Stäfa, 31 March 2021



Glenn Borrett
Senior Manager Regulatory Affairs

Product Name, Model (Reference number)

scala B5-R (REF: 050-6408-R872)
scala B5-312 (REF: 050-6402-R872)
scala B3-R (REF: 050-6407-R872)
scala B3-312 (REF: 050-6401-R872)
scala B-R trial (REF: 050-6411-P772)
scala B-312 trial (REF: 050-6405-P772)
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SoniTon UP6 20 312 (REF: 050-6403-xxxx)
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Selectic Ocean R5-R (REF:050-0440)

*xx denotes region