

# DECLARATION OF CONFORMITY (RED)

(Manufacturer's Declaration)

**Manufacturer:** **Bernafon AG**  
Morgenstrasse 131, CH-3018 Bern, Switzerland,  
Telephone +41 31 998 15 15

**Products:**

- Family:** Zerena
- Models:** Zerena (ZR) 9, Zerena (ZR) 7, Zerena (ZR) 5, Zerena (ZR) 3,  
Zerena (ZR) 1
- Styles:** miniRITE (NMR), miniRITE T (MNR T), BTE 105 (B 105)

The Manufacturer declares under its sole responsibility that the listed hearing aid models and styles are in conformity with the essential requirements and other relevant requirements of the following Directives and Regulations:

*Radio Equipment Directive 2014/53/EU with applied Medical Device Directive MDD 93/42/EEC standards and council recommendation 1999/519/EC on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz).*

**Standard(s) Applied in Full:**

*Health and Safety Article 3.1a:*

EN 62479:2010  
EN 60601-1:2006 + Corr.: 2006 + AM1:2013  
IEC 60601-2-66:2015 / Draft EN 60601-2-66:2018  
EN 60601-1-6:2010 + AM1:2015 / EN 62366:2008 + AM1:2015

*Electromagnetic Compatibility (EMC) Article 3.1b:*

Draft EN 301 489 -1 v.2.2.0  
Final draft EN 301 489-3 v.2.1.1  
Draft EN 301 489-17 v.3.2.0  
EN 60601-1-2:2016 / IEC 60601-1-2:2014  
IEC 60118-13:2016

*Radio Spectrum Matters Article 3.2:*

EN 300 328 v.2.1.1  
EN 300 330 v.2.1.1  
EN 300 422-4 v.2.1.1 with the use of NSH 7<sup>th</sup> edition.

Testing performed by CTC advanced GmbH, Untertürkheimer Strasse 6–10, 66117 Saarbrücken, Germany.  
RED directive conformity assessment by Bernafon AG.



Signed in Smørum, Denmark, 2018-08-15 on behalf of Bernafon AG.

Asif Muhammad

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Director, Regulatory Affairs