

# DECLARATION OF CONFORMITY (RED)

(Manufacturer's Declaration)

Manufacturer: Bernafon AG, Morgenstrasse 131, CH-3018 Bern, Switzerland,  
Telephone +41 31 998 15 15, Fax +41 31 998 15 90

The Manufacturer declares under its sole responsibility that the following hearing aids:

**Family:** Bernafon Zerena (ZR)  
**Models:** ZR9, ZR7, ZR5, ZR3, ZR1  
**Styles:** CIC, IIC, ITC, ITE HS, ITE FS

are in conformity with the essential requirements and other relevant requirements of the following Directives and Regulations:

Radio Equipment Directive 2014/53/EU 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 Organization:**

CTC advanced GmbH, Untertürkheimer Strasse 6–10, 66117 Saarbrücken, Germany

Signed in Smørum, Denmark, 2018-08-14 on behalf of Bernafon AG.

Asif Muhammad

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Director, Regulatory Affairs

