

DECLARATION OF CONFORMITY (RED)

(Manufacturer's Declaration)

Manufacturer: **Sonic Innovations, Inc.**
2501 Cottontail Lane, Somerset, NJ 08873, USA,
Telephone: +1 888 423 7834

Products:

- Family:** Enchant
- Models:** Enchant (ET) 100, Enchant (ET) 80, Enchant (ET) 60, Enchant (ET) 40, Enchant (ET) 20
- Styles:** miniRITE (MNR), 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 7th edition.

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



Signed in Smørum, Denmark, 2018-08-15 on behalf of Sonic Innovations, Inc.

Asif Muhammad

Director, Regulatory Affairs