

DECLARATION OF CONFORMITY (RED)

(Manufacturer's Declaration)

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

Products: **Brand:** Sonic
Family: Captivate
Models: Captivate 100 (CV100), Captivate 80 (CV80), Captivate 60 (CV60),
Captivate 40 (CV40), Captivate 20 (CV20)
Styles: miniRITE T R (MNR T R)

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 (Telecoil)

Testing performed by CTC advanced GmbH, Untertürkheimer Strasse 6–10, 66117 Saarbrücken, Germany and UL International Demko A/S Borupvang 5A, DK-2750 Ballerup, Denmark.

RED directive conformity assessment by Sonic Innovations Inc.

Signed in Smørum, Denmark, 2020-02-20 on behalf of Sonic Innovations, Inc.

Asif Muhammad

Asif Muhammad
Director, Regulatory Affairs