

DECLARATION OF CONFORMITY (RED)

(Manufacturer's Declaration)

Manufacturer: **Oticon A/S**

Kongebakken 9, DK-2765 Smørum, Denmark

Telephone: +45 39 17 71 00

Products:

Family: Oticon Opn

Models: Opn 1, Opn 2, Opn 3, Siya 1, Siya 2

Styles: miniRITE (MNR), miniRITE T (MNR T), BTE13, BTE13 PP (P)

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 Oticon A/S



Signed in Smørum, Denmark, 2018-08-14

Per Klaus Nielsen
Regulatory Affairs Officer, QARA