

DECLARATION OF CONFORMITY (RED)

(Manufacturer's Declaration)

Manufacturer: Oticon A/S, Kongebakken 9, DK-2765 Smørum, Denmark
Telephone: +45 39 17 71 00, Fax +45 39 27 79 00

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

Family: Oticon Opn, Siya
Models: Opn 1, Opn 2, Opn3, Siya 1, Siya 2
Styles: IIC, CIC, 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 7th edition

Testing Organization:

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

Signed in Smørum, Denmark, 2018-08-13 on behalf of Oticon A/S.



Ole Myrtue
Regulatory Affairs Officer



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PEOPLE FIRST