

DECLARATION OF CONFORMITY (RED)

(Manufacturer's Declaration)

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

Products: **Brand:** Oticon
Product Name: Oticon CROS
Model Name: CROS01

The Manufacturer declares under its sole responsibility that the listed model for accessory to wireless hearing aids is 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
IEC 60601-1: 2005 + Cor. 1:2006 + Cor. 2:2007 + A1:2012
and EN 60601-1:2006 + Cor. :2010 + A1:2013
IEC 60601-1-6:2010 + A1:2013 and EN 60601-1-6:2010 + A1:2015 /
IEC 62366:2007 + A1:2014 and EN 62366:2008 + A1:2015
IEC 60601-2-66:2015 / Draft EN 60601-2-66:2018

Electromagnetic Compatibility (EMC) Article 3.1b:

Draft EN 301 489-1 v.2.2.1
EN 301 489-3 v.2.1.1
IEC 60601-1-2:2014 / DIN EN 60601-1-2:2016

Radio Spectrum Matters Article 3.2:

Final draft EN 300 330 v.2.1.1

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, 2019-08-09



Jean Claude Kanyarubungo
Regulatory Affairs Manager