oticon MEDICAL | Because sound matters

EU Declaration of Conformity

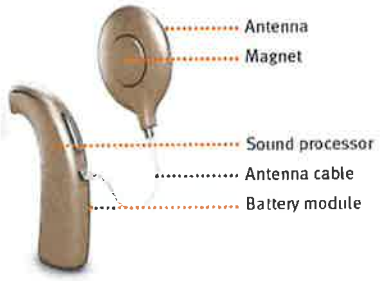
(according to EN ISO/IEC 17050-1:2010)

Manufacturer's name: **NEURELEC**
Manufacturer's address: 2720, Chemin St Bernard
06620 Vallauris
France

Name of the device: **Neuro 2**
Device type: Sound processor for a cochlear implant system

Product identification :

158004	Neuro 2 (Zti), C044* (Silver)
158028	Neuro 2 (Zti), C057*(Power Pink)
158031	Neuro 2 (Zti), C058*(Aquamarine)
157975	Neuro 2 (Zti), C063*(Diamond Blacl
152390	Neuro 2 (Zti), C090*(Chroma Beige
158034	Neuro 2 (Zti), C091*(Silver Grey)
158014	Neuro 2 (Zti), C092*(Steel Grey)
157981	Neuro 2 (Zti), C093*(Chesnut Brow
165439	Neuro 2 (Zti), C094*(Terracotta)
165440	Neuro 2 (Zti), C098*(Pure White)



NEURELEC ensures and declares under its sole responsibility that devices specified above are in conformity with the essential requirements of the following Union harmonization legislations as amended and implemented in the countries where devices are sold:

Documents No.	Title	Edition
2014/53/EU	Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (RED)	16 Apr. 2014
1999/519/EC	Council Recommendation of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz)	12 Jul. 1999

Any modification of the Neuro 2 Sound Processor not authorised by the manufacturer will invalidate this declaration.

Standard(s) Applied in Full or partially:

Article 3.1a:	EN 50665:2017	Test report No.: 1-4954/17-01-03 issued by CTC Advanced
(Health)	EN 62311:2008	Test report No.: 1-4954/17-01-03 issued by CTC Advanced
Article 3.1b:	EN 301 489-1 v.2.2.0:2017	Test report No.: 1-4069/17-01-04 issued by CTC Advanced
(EMC)	EN 301 489-3 v.2.1.1:2016	Test report No.: 1-4069/17-01-04 issued by CTC Advanced
Article 3.2	EN 300 330 v.2.1.1:2016	Test report No.: 1-4069/17-01-03 issued by CTC Advanced
(Radio spectrum)	NSH-7:2007 (Clause 5.7)	Test report No.: 1-4069/17-01-05-B issued by CTC Advanced

Additional information
The chosen route to CE marking is conforming to Annex II of Directive 2014/53/EU.
The tests have been conducted by CTC advanced GmbH, Untertürkheimer Strasse 6–10, 66117 Saarbrücken, Germany (Notified Body Identification Number: 0682), that meets essential requirements of the Directive 2014/53/EU.

Signed for and on behalf of Neurelec

Vallauris, 04 October 2019

Fabrice LAMOUR, Senior Director QARA

CE

Oticon Medical
/Neurelec

Neurelec
2720 Chemin St Bernard
06220 Vallauris
France

Tel: +33 4 93 95 18 18
Fax : +33 4 93 95 38 01
info@oticonmedical.com
www.oticonmedical.com

RCS Antibes 487 829 574
SIRET 487 829 574 00010
NAF 7211Z
S.A.S. au capital de 1.000.000 €