oticon MEDICAL | Because sound matters

EU Declaration of Conformity

(Legal manufacturer's declaration)

Legal Manufacturer

Name:	**OTICON MEDICAL**
Address:	**2720 chemin Saint-Bernard 06620 VALLAURIS FRANCE**
SRN:	**FR-MF-000003246**

Name of the device(s):

Premium, C044 Neuro2
Premium, C057 Neuro2
Premium, C058 Neuro2
Premium, C063 Neuro2
Premium, C090 Neuro2
Premium, C091 Neuro2
Premium, C092 Neuro2
Premium, C093 Neuro2
Premium, C094 Neuro2
Premium, C098 Neuro2
Disposable, C063 Neuro2
Disposable, C090 Neuro2
Disposable, C093 Neuro2
Rechargeable, C063 Neuro2
Rechargeable, C090 Neuro2
Rechargeable, C093 Neuro2
Operating, Room Kit Neuro2
Swim Antenna, LD C068 Neuro2
Swim Antenna, SD C068 Neuro2

Device(s) identification : See Appendix I

Device(s) intended purpose:

The Neuro 2 sound processor, when used with a compatible Neuro cochlear implant, is intended to restore hearing for people with sensorineural hearing loss in the daily living environment.

The Swim Antenna is an accessory of the Neuro 2 sound processor, intended to be used in combination with the Swim Sleeves Kit to provide an extended protection to the Neuro 2 sound processor while used in water, humid and dusty environments.

The Neuro 2 Operating Room Kit sound processor is intended to allow audiologists and clinical supports to perform objective measurements in the operating room.

OTICON MEDICAL ensures and declares under its sole responsibility that devices specified above are in conformity with the requirements of the following Union harmonisation legislations as amended and implemented in the member states where devices are sold:

Documents No.	Title	Edition
2017/745 [MDR – M5]	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, and its amendments	9. Jul. 2024
2014/53/EU [RED – M3]	Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC, and its amendments	11. Sep. 2023
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
2011/65/EU [ROHS – M85]	DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and its amendments	21 May 2024

Conformity is assessed according to:

- ☒ Regulation (EU) No 2017/745, Article 52 and the Annex IX – Conformity Assessment based on quality management and on assessment of technical documentation, chapter I, II and III and is supported by the EU certificates G12 112859 0003 rev. 00 and G70 112859 0001 rev. 02, issued by TÜV SÜD (0123).
- ☒ Directive 2014/53/EU, Article 17 – § 2(a), following Annex II – Internal production control.
- ☒ Directive 2011/65/EU, Article 7.

The devices specified in APPENDIX I are compliant with the standards listed in APPENDIX II.

Signed for and on behalf of OTICON MEDICAL

OTICON MEDICAL
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Vallauris, 4 November 2025

Approved by the Person Responsible for Regulatory Compliance,

Stephanie AGNONA
Sr. Manager QARA

This Declaration of Conformity is valid until replaced by a new revision, but no longer than August 29, 2028. Any modification of the device not authorised by OTICON MEDICAL will invalidate this declaration.

APPENDIX I

This appendix lists the devices and associated accessories covered by the present declaration:

Table 1: Identification of the devices and its accessories (ACC)

Device Type	Reference	Designation	Basic UDI-DI	Class and classification rule MDR EMDN Code
Device	231761	PREMIUM, C044 NEURO2	3663227SND0001N3	Class III (Rule 9 - Paragraph 4) J0380 – Auditory Active – Implantable Devices - Accessories
Device	231897	PREMIUM, C057 NEURO2	3663227SND0001N3	Class III (Rule 9 - Paragraph 4) J0380 – Auditory Active – Implantable Devices - Accessories
Device	231898	PREMIUM, C058 NEURO2	3663227SND0001N3	Class III (Rule 9 - Paragraph 4) J0380 – Auditory Active – Implantable Devices - Accessories
Device	231900	PREMIUM, C063 NEURO2	3663227SND0001N3	Class III (Rule 9 - Paragraph 4) J0380 – Auditory Active – Implantable Devices - Accessories
Device	231902	PREMIUM, C090 NEURO2	3663227SND0001N3	Class III (Rule 9 - Paragraph 4) J0380 – Auditory Active – Implantable Devices - Accessories
Device	231904	PREMIUM, C091 NEURO2	3663227SND0001N3	Class III (Rule 9 - Paragraph 4) J0380 – Auditory Active – Implantable Devices - Accessories
Device	231909	PREMIUM, C092 NEURO2	3663227SND0001N3	Class III (Rule 9 - Paragraph 4) J0380 – Auditory Active – Implantable Devices - Accessories
Device	231912	PREMIUM, C093 NEURO2	3663227SND0001N3	Class III (Rule 9 - Paragraph 4) J0380 – Auditory Active – Implantable Devices - Accessories
Device	231914	PREMIUM, C094 NEURO2	3663227SND0001N3	Class III (Rule 9 - Paragraph 4) J0380 – Auditory Active – Implantable Devices - Accessories
Device	231915	PREMIUM, C098 NEURO2	3663227SND0001N3	Class III (Rule 9 - Paragraph 4) J0380 – Auditory Active – Implantable Devices - Accessories
Device	231916	DISPOSABLE, C063 NEURO2	3663227SND0003N7	Class III (Rule 9 - Paragraph 4) J0380 – Auditory Active – Implantable Devices - Accessories
Device	231917	DISPOSABLE, C090 NEURO2	3663227SND0003N7	Class III (Rule 9 - Paragraph 4) J0380 – Auditory Active – Implantable Devices - Accessories
Device	231918	DISPOSABLE, C093 NEURO2	3663227SND0003N7	Class III (Rule 9 - Paragraph 4) J0380 – Auditory Active – Implantable Devices - Accessories
Device	231919	RECHARGEABLE, C063 NEURO2	3663227SND0002N5	Class III (Rule 9 - Paragraph 4) J0380 – Auditory Active – Implantable Devices - Accessories
Device	231920	RECHARGEABLE, C090 NEURO2	3663227SND0002N5	Class III (Rule 9 - Paragraph 4) J0380 – Auditory Active – Implantable Devices - Accessories
Device	231921	RECHARGEABLE, C093 NEURO2	3663227SND0002N5	Class III (Rule 9 - Paragraph 4) J0380 – Auditory Active – Implantable Devices - Accessories
Device	231922	OPERATING, ROOM KIT NEURO2	3663227SND0004N9	Class III (Rule 9 - Paragraph 4) J0380 – Auditory Active – Implantable Devices - Accessories
ACC	231913	SWIM ANTENNA, LD C068 NEURO2	3663227SND0005NB	Class III (Rule 9 - Paragraph 4) J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232215	SWIM ANTENNA, SD C068 NEURO2	3663227SND0006ND	Class III (Rule 9 - Paragraph 4) J0380 – Auditory Active – Implantable Devices - Accessories

APPENDIX II

Legislation	Means of compliance
Directive n°2014/53/UE (RED)	
Article 3.1a:	EN 50665:2017
(Health)	EN 62311:2020
Article 3.1b:	ETSI EN 301 489-1 V2.2.3:2019
(EMC)	ETSI EN 301 489-3 V2.1.1:2017
Article 3.2	ETSI EN 300 330 V2.1.1:2016
(Radio spectrum)	ETSI EN 300 422-4 V2.1.1:2017
	NHS 7.0:2007 (Chapter 5.7)
Directive n°2011/65/EU (RoHS)	
	EN IEC 63000:2018