

Legal Manufacturer

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

Name of the device(s):
Tamper Tool, Neuro 2
Safety Line, Neuro 2
Earplug Retention Kit, Neuro 2
Clip, Neuro 2
Thin Safety Line, Neuro 2
Care Kit, Neuro 2
Swim Sleeves Kit, Neuro 2
Charger Station, Neuro 2
Programming Device, Right Wired Red
Programming Device, Left Wired Blue
Antenna Cable, Packed 280mm Transparent Neuro2
Antenna Magnet, Strength-0.5 C063 Neuro2
Antenna Magnet, Strength-0.5 C094 Neuro2
Antenna Magnet, Strength-0.5 C093 Neuro2
Antenna Magnet, Strength-0.5 C092 Neuro2
Antenna Magnet, Strength- 0.5 C091 Neuro2
Antenna Magnet, Strength-0.5 C044 Neuro2
Antenna Magnet, Strength-0.5 C098 Neuro2
Antenna Magnet, Strength-0.5 C058 Neuro2
Antenna Magnet, Strength-0.5 C057 Neuro2
Antenna Magnet, Strength-0.5 C090 Neuro2
Antenna Magnet, Strength-2 C063 Neuro2
Antenna Magnet, Strength-2 C094 Neuro2
Antenna Magnet, Strength-2 C093 Neuro2
Antenna Magnet, Strength-2 C092 Neuro2
Antenna Magnet, Strength-2 C091 Neuro2
Antenna Magnet, Strength-2 C044 Neuro2
Antenna Magnet, Strength-2 C098 Neuro2
Antenna Magnet, Strength-2 C058 Neuro2
Antenna Magnet, Strength-2 C057 Neuro2
Antenna Magnet, Strength-2 C090 Neuro2
Antenna Magnet, Strength-4 C063 Neuro2
Antenna Magnet, Strength-4 C094 Neuro2
Antenna Magnet, Strength-4 C093 Neuro2
Antenna Magnet, Strength-4 C092 Neuro2
Antenna Magnet, Strength-4 C091 Neuro2
Antenna Magnet, Strength-4 C044 Neuro2
Antenna Magnet, Strength-4 C098 Neuro2
Antenna Magnet, Strength-4 C058 Neuro2
Antenna Magnet, Strength-4 C057 Neuro2
Antenna Magnet, Strength-4 C090 Neuro2
Antenna Magnet, Strength-5 C063 Neuro2
Antenna Magnet, Strength-5 C094 Neuro2

Antenna Magnet, Strength-5 C093 Neuro2
Antenna Magnet, Strength-5 C092 Neuro2
Antenna Magnet, Strength-5 C091 Neuro2
Antenna Magnet, Strength-5 C044 Neuro2
Antenna Magnet, Strength-5 C098 Neuro2
Antenna Magnet, Strength-5 C058 Neuro2
Antenna Magnet, Strength-5 C057 Neuro2
Antenna Magnet, Strength-5 C090 Neuro2
Antenna Magnet, Strength-8 C063 Neuro2
Antenna Magnet, Strength-8 C094 Neuro2
Antenna Magnet, Strength-8 C093 Neuro2
Antenna Magnet, Strength-8 C092 Neuro2
Antenna Magnet, Strength-8 C091 Neuro2
Antenna Magnet, Strength-8 C044 Neuro2
Antenna Magnet, Strength-8 C098 Neuro2
Antenna Magnet, Strength-8 C058 Neuro2
Antenna Magnet, Strength-8 C057 Neuro2
Antenna Magnet, Strength-8 C090 Neuro2

Device(s) identification : See Appendix I

Device(s) intended purpose :

The Tamper Tool, Neuro 2 is an accessory intended to secure the Neuro 2 sound processor battery modules.

The Safety Line, Neuro 2 is an accessory intended to prevent loss of the Neuro 2 sound processor when it falls off the ear.

The Earplug Retention Kit, Neuro 2 is an accessory intended to improve the retention of the Neuro 2 sound processor on the ear.

The Clip, Neuro 2 is an accessory intended to provide an off-the-ear wearing option for the Neuro 2 sound processor.

The Thin Safety Line, Neuro 2 is an accessory intended to prevent loss of the Neuro 2 sound processor when it falls off the ear.

The care kit, Neuro 2 is an accessory that includes:

- A cloth, intended to allow cleaning of the Neuro 2 sound processor;
- A pouch, intended to allow storage of a spare battery module of the Neuro 2 sound processor;
- A pin tool, intended to allow changing the Neuro 2 sound processor hook. It is accompanied with spare hook pins.

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

The Charger Station, Neuro 2 is an accessory intended to recharge the Neuro 2 rechargeable batteries.

The Programming device, Right Wired Red and the Programming Device, Left Wired Blue are accessories intended to connect the Neuro 2 sound processor to the CI-Link fitting interface to enable fitting Neuro 2 sound processor with Genie Medical CI fitting software.

The antenna cable 280 mm is an accessory intended to connect the Neuro 2 sound processor to the Neuro 2 antenna and is intended to provide a contralateral ear wearing option for the Neuro 2 sound processor, or to be used in combination with the Clip to provide an off-the-ear wearing option for the Neuro 2 sound processor.

The antenna magnet is an accessory intended to align and hold the Neuro 2 antenna in front of the Neuro Zti implant.

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	9. Jul. 2024
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	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 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

Vallauris, 4 November 2025

Approved by the Person Responsible for Regulatory Compliance,

Stephanie AGNONA
Sr. Manager QARA

S. Agnona

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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
ACC	226158	TAMPER TOOL, NEURO2	3663227SND0012N8	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	226117	SAFETY LINE, NEURO2	3663227SND0013NA	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	226110	EARPLUG RETENTION KIT, NEURO2	3663227SND0008NH	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	226109	CLIP, NEURO2	3663227SND0009NK	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	226159	THIN SAFETY LINE, NEURO2	3663227SND0010N4	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	226099	CARE KIT, NEURO2	3663227SND0014NC	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	230731	SWIM SLEEVES KIT, NEURO2	3663227SND0007NF	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	226100	CHARGER STATION, NEURO2	3663227SND0011N6	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	226115	PROGRAMMING DEVICE, RIGHT WIRED RED	3663227SND0015NE	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	226114	PROGRAMMING DEVICE, LEFT WIRED BLUE	3663227SND0015NE	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	230113	ANTENNA CABLE, PACKED 280MM TRANSPARENT NEURO2	3663227SND0021N9	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232229	ANTENNA MAGNET, STRENGTH-0.5 C063 NEURO2	3663227SND0020N7	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	230084	ANTENNA MAGNET, STRENGTH-0.5 C094 NEURO2	3663227SND0020N7	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232237	ANTENNA MAGNET, STRENGTH-0.5 C093 NEURO2	3663227SND0020N7	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232260	ANTENNA MAGNET, STRENGTH-0.5 C092 NEURO2	3663227SND0020N7	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232252	ANTENNA MAGNET, STRENGTH- 0.5 C091 NEURO2	3663227SND0020N7	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232244	ANTENNA MAGNET, STRENGTH-0.5 C044 NEURO2	3663227SND0020N7	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232284	ANTENNA MAGNET, STRENGTH-0.5 C098 NEURO2	3663227SND0020N7	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232268	ANTENNA MAGNET, STRENGTH-0.5 C058 NEURO2	3663227SND0020N7	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232276	ANTENNA MAGNET, STRENGTH-0.5 C057 NEURO2	3663227SND0020N7	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories

Device Type	Reference	Designation	Basic UDI-DI	Class and classification rule MDR EMDN Code
ACC	232220	ANTENNA MAGNET, STRENGTH-0.5 C090 NEURO2	3663227SND0020N7	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232231	ANTENNA MAGNET, STRENGTH-2 C063 NEURO2	3663227SND0019NN	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	230086	ANTENNA MAGNET, STRENGTH-2 C094 NEURO2	3663227SND0019NN	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232239	ANTENNA MAGNET, STRENGTH-2 C093 NEURO2	3663227SND0019NN	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232262	ANTENNA MAGNET, STRENGTH-2 C092 NEURO2	3663227SND0019NN	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232254	ANTENNA MAGNET, STRENGTH-2 C091 NEURO2	3663227SND0019NN	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232246	ANTENNA MAGNET, STRENGTH-2 C044 NEURO2	3663227SND0019NN	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232286	ANTENNA MAGNET, STRENGTH-2 C098 NEURO2	3663227SND0019NN	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232270	ANTENNA MAGNET, STRENGTH-2 C058 NEURO2	3663227SND0019NN	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232278	ANTENNA MAGNET, STRENGTH-2 C057 NEURO2	3663227SND0019NN	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232222	ANTENNA MAGNET, STRENGTH-2 C090 NEURO2	3663227SND0019NN	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232233	ANTENNA MAGNET, STRENGTH-4 C063 NEURO2	3663227SND0018NL	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	230091	ANTENNA MAGNET, STRENGTH-4 C094 NEURO2	3663227SND0018NL	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232243	ANTENNA MAGNET, STRENGTH-4 C093 NEURO2	3663227SND0018NL	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232267	ANTENNA MAGNET, STRENGTH-4 C092 NEURO2	3663227SND0018NL	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232259	ANTENNA MAGNET, STRENGTH-4 C091 NEURO2	3663227SND0018NL	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232251	ANTENNA MAGNET, STRENGTH-4 C044 NEURO2	3663227SND0018NL	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232291	ANTENNA MAGNET, STRENGTH-4 C098 NEURO2	3663227SND0018NL	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232275	ANTENNA MAGNET, STRENGTH-4 C058 NEURO2	3663227SND0018NL	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232283	ANTENNA MAGNET, STRENGTH-4 C057 NEURO2	3663227SND0018NL	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232228	ANTENNA MAGNET, STRENGTH-4 C090 NEURO2	3663227SND0018NL	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232234	ANTENNA MAGNET, STRENGTH-5 C063 NEURO2	3663227SND0017NJ	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories

Device Type	Reference	Designation	Basic UDI-DI	Class and classification rule MDR EMDN Code
ACC	230088	ANTENNA MAGNET, STRENGTH-5 C094 NEURO2	3663227SND0017NJ	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232241	ANTENNA MAGNET, STRENGTH-5 C093 NEURO2	3663227SND0017NJ	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232264	ANTENNA MAGNET, STRENGTH-5 C092 NEURO2	3663227SND0017NJ	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232256	ANTENNA MAGNET, STRENGTH-5 C091 NEURO2	3663227SND0017NJ	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232248	ANTENNA MAGNET, STRENGTH-5 C044 NEURO2	3663227SND0017NJ	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232288	ANTENNA MAGNET, STRENGTH-5 C098 NEURO2	3663227SND0017NJ	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232272	ANTENNA MAGNET, STRENGTH-5 C058 NEURO2	3663227SND0017NJ	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232280	ANTENNA MAGNET, STRENGTH-5 C057 NEURO2	3663227SND0017NJ	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232224	ANTENNA MAGNET, STRENGTH-5 C090 NEURO2	3663227SND0017NJ	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232236	ANTENNA MAGNET, STRENGTH-8 C063 NEURO2	3663227SND0016NG	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	230090	ANTENNA MAGNET, STRENGTH-8 C094 NEURO2	3663227SND0016NG	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232242	ANTENNA MAGNET, STRENGTH-8 C093 NEURO2	3663227SND0016NG	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232266	ANTENNA MAGNET, STRENGTH-8 C092 NEURO2	3663227SND0016NG	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232258	ANTENNA MAGNET, STRENGTH-8 C091 NEURO2	3663227SND0016NG	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232250	ANTENNA MAGNET, STRENGTH-8 C044 NEURO2	3663227SND0016NG	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232290	ANTENNA MAGNET, STRENGTH-8 C098 NEURO2	3663227SND0016NG	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232274	ANTENNA MAGNET, STRENGTH-8 C058 NEURO2	3663227SND0016NG	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232282	ANTENNA MAGNET, STRENGTH-8 C057 NEURO2	3663227SND0016NG	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories
ACC	232226	ANTENNA MAGNET, STRENGTH-8 C090 NEURO2	3663227SND0016NG	Class III / Rule 8 / Indent 6 J0380 – Auditory Active – Implantable Devices - Accessories

APPENDIX II

Legislation	Means of compliance
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Directive n°2011/65/EU (RoHS)	
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	EN 50581:2012
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Regulation (EU) No 2017/745	
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	EN ISO 13485:2016/A11 :2021
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	EN ISO 10993-10:2023
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	EN ISO 10993-12:2021
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	EN ISO 10993-18:2020
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	EN ISO 10993-23:2021
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	EN ISO 15223-1:2021
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	EN ISO 14971:2019
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