

Reference: D2360079 Rev. 3
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System/Procedure Pack Producer

Name: **OTICON MEDICAL**
Address: **2720 chemin Saint-Bernard**
06620 VALLAURIS
FRANCE
SRN: **FR-PR-000003247**

Name of the System(s) / Procedure Pack(s): ***Sound Processor Neuro 2 and Swim Kit
procedure Packs***
System(s) /Procedure Pack(s) identification: **See Appendix I**

OTICON MEDICAL declares that:

- OTICON MEDICAL has verified the mutual compatibility of the devices and products part of the System(s) /Procedure pack(s) covered by this declaration in accordance with the manufacturers' instructions and has carried out the activities in accordance with these instructions; and
- OTICON MEDICAL has packaged the system or procedure pack and supplied relevant information to users incorporating the information that has been supplied by the manufacturers of the devices and products which have been put together; and
- OTICON MEDICAL has subjected the system or procedure pack to appropriate methods of internal monitoring, verification, and validation.
- All the System(s) /Procedure pack(s) covered by the present declaration comply with the requirements of Article 22 of Medical Device Regulation (EU MDR) 2017/745.

This product has been originally declared in compliance with Article 22 of EU MDR 2017/745 on:

- 30/08/2023 for Swim Antenna and Neuro 2 sound processor (G70 112859 0001 Rev. 00)
- 23/05/2024 (G70 112859 0001 Rev. 01) and 05/03/2025 (G70 112859 0001 Rev. 02) for Accessories

Signed for and on behalf of OTICON MEDICAL

Vallauris, *4 November 2025*

S. Annona

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Approved by the Person Responsible for Regulatory Compliance,

Stephanie ANNONA
Sr. Manager QARA

APPENDIX I

This appendix lists the Systems/Procedure packs covered by the present declaration:

Table 1: Identification of the systems/procedure packs

<i>System or Procedure Pack</i>	<i>Reference</i>	<i>Designation</i>	<i>Basic UDI-DI</i>
Procedure Pack	231923	PREMIUM, COMPLETE SET C044 NEURO2	3663227PAC0003EY
Procedure Pack	231924	PREMIUM, COMPLETE SET C057 NEURO2	3663227PAC0003EY
Procedure Pack	231925	PREMIUM, COMPLETE SET C058 NEURO2	3663227PAC0003EY
Procedure Pack	231926	PREMIUM, COMPLETE SET C063 NEURO2	3663227PAC0003EY
Procedure Pack	231927	PREMIUM, COMPLETE SET C090 NEURO2	3663227PAC0003EY
Procedure Pack	231928	PREMIUM, COMPLETE SET C091 NEURO2	3663227PAC0003EY
Procedure Pack	231930	PREMIUM, COMPLETE SET C092 NEURO2	3663227PAC0003EY
Procedure Pack	231931	PREMIUM, COMPLETE SET C093 NEURO2	3663227PAC0003EY
Procedure Pack	231933	PREMIUM, COMPLETE SET C094 NEURO2	3663227PAC0003EY
Procedure Pack	231934	PREMIUM, COMPLETE SET C098 NEURO2	3663227PAC0003EY
Procedure Pack	232071	ESSENTIALS RC, COMPLETE SET C063 NEURO2	3663227PAC0004F2
Procedure Pack	232072	ESSENTIALS RC, COMPLETE SET C090 NEURO2	3663227PAC0004F2
Procedure Pack	232073	ESSENTIALS RC, COMPLETE SET C093 NEURO2	3663227PAC0004F2
Procedure Pack	232068	ESSENTIALS D, COMPLETE SET C063 NEURO2	3663227PAC0005F4
Procedure Pack	232069	ESSENTIALS D, COMPLETE SET C090 NEURO2	3663227PAC0005F4
Procedure Pack	232070	ESSENTIALS D, COMPLETE SET C093 NEURO2	3663227PAC0005F4
Procedure Pack	226138	SWIM KIT SD 0.5, NEURO2	3663227PAC0006F6
Procedure Pack	226139	SWIM KIT SD 1, NEURO2	3663227PAC0006F6
Procedure Pack	226140	SWIM KIT SD 2, NEURO2	3663227PAC0006F6
Procedure Pack	226141	SWIM KIT LD 1, NEURO2	3663227PAC0007F8
Procedure Pack	226142	SWIM KIT LD 2, NEURO2	3663227PAC0007F8
Procedure Pack	226143	SWIM KIT LD 3, NEURO2	3663227PAC0007F8
Procedure Pack	226144	SWIM KIT LD 4, NEURO2	3663227PAC0007F8
Procedure Pack	226145	SWIM KIT LD 5, NEURO2	3663227PAC0007F8
Procedure Pack	226146	SWIM KIT LD 6, NEURO2	3663227PAC0007F8
Procedure Pack	226147	SWIM KIT LD 8, NEURO2	3663227PAC0007F8