

EU Declaration of Conformity Orbit+ NeurooQuest

This EU Declaration of Conformity has been drafted according to the requirements laid out in REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL including Amendment M1 from 2020-04-24.

Link here: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0745-20200424>

List of Abbreviations

Abbreviation	Explanation
CEO	Chief executive officer
EMDN	European Medical Device Nomenclature
SRN	Single Registration Number

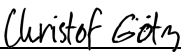
Conformity assessment procedure: Appendix IX of the REGULATION (EU) 2017/745.

The Medical Device referenced in this document meets the provisions of the REGULATION (EU) 2017/745 for Medical Devices.

Name of the Product	Orbit	NeurooQuest
SRN	AT-MF-000022440	
EMDN product code	Z121003	Z12100392
Type	4 Channel EEG	Neurofeedback Software
Basic UDI-DI	918000413OrbitND	918000413NAMG01YJ
Classification	IIa, according to Rule 10	IIa, according to Rule 11

Applied Regulations and Standards	<ul style="list-style-type: none"> • Österreichisches Medizinproduktegesetz 2021 • REGULATION (EU) 2017/745 (MDR) • DIRECTIVE 2014/53/EU (RED) • ISO 13485 • ISO 15223-1 • ISO 14971 • ISO 20417 • ISO 80601-2-26 • IEC 10993-1 • IEC 60601-1 • IEC 60601-1-2 • IEC 60601-1-6 • IEC 60601-1-9 • IEC 60601-1-12 • IEC 62304 • IEC 62133-2 • IEC 62366 -1 	<ul style="list-style-type: none"> • Österreichisches Medizinproduktegesetz 2021 • REGULATION (EU) 2017/745 (MDR) • REGULATION (EU) 2016/679 (GDPR) • ISO 13485 • ISO 15223-1 • ISO 14971 • IEC 62304 • IEC 62366 -1 • IEC 82304-1
Notified Body	<p>TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstraße 65 80339 München</p> <p>Identification Number: CE 0123</p> <p>Certificate Nr. Q5 108908 0001 Rev. 00</p>	
Manufacturer	<p>Brainhero GmbH - Fuchsthallergasse 2/10 - 1090 Wien - Austria Phone: +43 1 997 4294 - email: help@brainhero.eu - www.brainhero.eu</p>	

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Issued by:	Christof Goetz the CEO of Brainhero on behalf of Brainhero GmbH
Place and Date:	04.11.2022
Signature:	<p style="text-align: center;">DocuSigned by:  CB5ED1D322D64CB...</p>