HeadApp/NEUROvitalis

EU Declaration of Conformity according to Regulation (EU) 2017/745 (MDR)

Product Information

Product: HeadApp/NEUROvitalis

Version: 2.x UDI-DI: 4270005126104

Manufacturer: HelferApp GmbH

Address: HelferApp GmbH, Zur Klus 31, 39175 Gommern OT Wahlitz, Germany

SRN: DE-MF-000004996 (EUDAMED)

Person Responsible according to Article 15 MDR: Frank Schulze

1. Declaration by the Manufacturer / Managing Director (Frank Schulze)

The manufacturer declares under its sole responsibility that the above-mentioned product meets all applicable requirements of Regulation (EU) 2017/745 on medical devices (MDR). This declaration is issued in accordance with Annex IV MDR.

2. Product Identification Product Name: HeadApp/NEUROvitalis

Software Type: Active non-invasive software medical device

Product Type: Digital software for providing structured cognitive training exercises

3. Intended Purpose

HeadApp/NEUROvitalis is digital software for performing structured cognitive training tasks. The software assists users in performing exercises aimed at general cognitive skills such as attention, memory, problem-solving, and language processing. HeadApp/NEUROvitalis does not provide diagnostic information, does not evaluate clinical pictures, and does not make therapeutic decisions. The software neither replaces medical treatment nor professional therapeutic services and serves exclusively to provide training content. The product is intended for use by adult and adolescent users as well as by healthcare professionals as part of general cognitive promotion.

4. Classification

The product is classified as a Class I medical device in accordance with MDR Annex VIII, Rule 11.

5. Applied Legal Regulations and Standards

Primary legal regulation:

- Regulation (EU) 2017/745 on medical devices (MDR)

Harmonised standards / applied specifications:

- EN ISO 14971:2019 — Risk management to medical devices
- IEC 62366-1:2015 — Usability engineering
- IEC 62304:2006 + AMD 1:2015 — Software life cycle processes (Class I)
- ISO 13485:2016 — Quality management systems (where applied)
- EN ISO 20417:2021 — Medical devices — Information to be supplied by the manufacturer

6. EUDAMED Registration

The manufacturer is registered as an economic operator in the EUDAMED system pursuant to Article 31 MDR.

SRN: DE-MF-000004996 (EUDAMED)

Role: Manufacturer ("Manufacturer")

The UDI data are deposited in EUDAMED.

7. Conformity Assessment Procedure

For the product, the self-certification procedure pursuant to MDR Annex IV in conjunction with Article 52(7) was applied. A Notified Body was not involved.

8. Retention and Documentation Obligation

The manufacturer holds all technical documentation pursuant to MDR Annex II and III available for at least 10 years after the last placing on the market.

9. Person Responsible according to Article 15 MDR

Frank Schulze confirms that the conformity of this product has been verified and all technical and regulatory requirements are fulfilled.

10. Signature

Place: Gommern
Date: 15.12. 2025
Name: Frank Schulze
Function: Managing Director

Signature: