



EU DECLARATION OF CONFORMITY, v1.0

A declaration of conformity issued under Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices.

Manufacturer:

MedDream UAB
K. Baršausko str. 59
LT-51423 Kaunas
Lithuania
SRN: LT-MF-000011782

Product: Stand-alone software medical device

Model: MedDream

Types: MedDream

Version: 8.9.1

Basic UDI-DI: 477904959MEDDREAMEE

UDI: (01)04779049590105(10)MDSY8910

GMDN: 41670

Notified body: TÜV Rheinland LGA Products GmbH

Class IIb active medical device according to MDR 2017/745 Annex VIII Chapter III, Rule 11.

We hereby declare that the above mentioned device meets the applicable provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices. Route of compliance according Annex IX Chapter I, Section 2 and 3 and Chapter III is applied. Issued certificate: registration No. HZ 2620158-1. All supporting technical documentation is retained at the premises of the manufacturer.

We hereby declare that the above mentioned device meets the applicable legislation:

Regulations (Class 2 according the below mentioned regulations in U.S., Brazil and Canada, class B according to the below mentioned regulation in Singapore):

- EU and Switzerland: Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices.
- U.K.: Medical Devices Regulations 2002 (SI 2002 No 618).
- Brazil: RDC ANVISA 665/2022 "Brazilian Medical Device Good Manufacturing Practices"; RDC ANVISA N. 67, OF 21 DECEMBER, 2009. General requirements for post-market surveillance; RDC ANVISA 551/2021 30 AUGUST, 2021. Brazilian Field Actions.
- Canada: Medical Devices Regulations – Part 1- SOR 98/282.
- U.S.: FDA Quality Management System Regulation (QMSR) 21 CFR 820 harmonized with ISO 13485:2016, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D.
- Singapore: Health Products (Medical Devices) Regulations 2010.

Harmonized standards:

- EN ISO 13485:2016, EN ISO 13485:2016 /AC:2018, EN ISO 13485:2016/ A11:2021. Medical devices – Quality management systems – Requirements for regulatory purposes
- ISO 14971:2019 + A11:2021. Medical devices – Application of risk management to medical devices
- IEC 62304:2006 + A1:2015. Software life cycle process
- IEC 62366-1 :2015 + AMD 1:2020. Application of usability engineering to medical devices
- EN 82304-1:2016. Health software. Part 1: General requirements for product safety
- IEC 81001-5-1:2021. Safety and effectiveness of healthcare software and healthcare information technology systems. Part 5-1: Security. Activities in the product life cycle

Manufacturer is exclusively responsible for the declaration of conformity.

Date of issue:

2026-10-01

Director of MedDream UAB
Vilma Khmaladze

Signed by:


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Place: Kaunas, Lithuania