medDream CE 0197

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: **8.7.0**
Basic UDI-DI: **477904959MEDDREAMEE**
UDI: **(01)04779049590105(10)MDSY8700**
GMDN: **40943**
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.: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D.
- Singapore: Health Products (Medical Devices) Regulations 2010.

Harmonized standards:

- 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:

2025-06-10

Place: Kaunas, Lithuania

Director of MedDream UAB
Tomas Dumbliauskas

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Tomas Dumbliauskas
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