Softneta
Medical imaging

CE 0197

EC DECLARATION OF CONFORMITY

Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices

Manufacturer:

UAB SOFTNETA
K. Barsausko str. 59B
LT-51423 Kaunas
Lithuania
SRN: LT-MF-000011782

Product: Stand-alone software medical device

Model: **«MedDream»**

Types: **«MedDream»**

Version: **8.3.0**

Basic UDI-DI: **477904959MEDDREAMEE**

UDI-DI: **(01)04779049590105(10)MDSY8300**

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 1992126-1. All supporting technical documentation is retained at the premises of the manufacturer.
Manufacturer is exclusively responsible for the declaration of conformity.

Date of issue:

2023-10-24

Director of Softneta
Vytautas Baublys

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Place: Kaunas, Lithuania