

EC DECLARATION OF CONFORMITY

Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Manufacturer:

UAB SOFTNETA
K. Barsausko str. 59B
LT-51423 Kaunas
Lithuania

Product: Stand-alone software medical device

Model: «MedDream»

Types: «MedDream»

Version: 8.2.0

UDI-DI: (01)04779049590105(10)MDSY8200

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:

2023-05-16

Director of Softneta
Vytautas Baublys

Place: Kaunas, Lithuania