Softneta
Medical imaging

CE 0197

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:

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

Product: Stand-alone software medical device

Model: **«MedDream»**

Types: **«MedDream»**

Version: **7.5.2**

UDI-DI: **(01)04779049590105(10)MDSY7520**

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

Date of issue:

2021-06-02

Director of Softneta
Vytautas Baublys