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: **7.7.0**

UDI-DI: **(01)04779049590105(10)MDSY7700**

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 VIII Chapter III, Rule 11 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:

2021-05-18

Director of Softneta
Vytautas Baublys