EC DECLARATION OF CONFORMITY

Manufacturer:

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

Product: Stand-alone software medical device

Model: «MedDream»

Types: «MedDream»

Version: 7.5.1

Notified body: DNV GL Nemko Presafe AS

Class IIa active medical device according to MDD 93/42/EEC and amendment 2007/47/EC to the Directive Article 11.3.a and Annex II excluding section 4 (Module H), Rule 10.

We hereby declare that the above mentioned device meets the applicable provisions of Council Directive 93/42/EEC concerning medical devices and amendment 2007/47/EC to the Directive. Route of compliance according Annex II excluding section 4 (Module H) 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: 2020-04-02

Director of Sofineta
Vytautos Baublys

Dokumentą elektroniniu parašu pasirašė
VYTAUTAS, BAUBLYS
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