Softneta
Medical imaging

CE 2460

EC DECLARATION OF CONFORMITY

Council Directive 93/42/EEC concerning medical devices and amendment 2007/47/EC to the Directive

Manufacturer:

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

Product: Stand-alone software medical device

Model: **«MedDream»**

Types: **«MedDream»**

Version: **7.1.1**

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:

2019-10-31

Director of Softneta
Vytautas Baublys

Dokumentą elektroniniu parašu pasirašė VYTAUTAS,BAUBLYS
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