

DECLARATION OF CONFORMITY



We,

TELEMED UAB

Highway Business Centre
Savanoriu pr. 178A
Vilnius LT-03154 Lithuania

Declare under our sole responsibility that:

Ultrasound scanners:

MicrUs Pro-C60S

MicrUs Pro-L40S

MicrUs Pro-L40N

Classification: **Class IIa** (in compliance with Annex II, Art.11 Medical Device Directive)
are in conformity with:

Essential Requirements of Council Directive 93/42/EEC (Medical Device Directive)

IEC 60601-1: 2005/A1:2012, Part 1: General requirements for basic safety and essential performance.

IEC 60601-1-2: 2014, Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: standard: Electromagnetic compatibility - Requirements and tests

IEC 60601-1-6:2010/A1:2013 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability

IEC 60601-2-37:2015 Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

IEC 60601-1-11:2010 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

ISO-10993-1:2009, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing within a risk management process.

ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity

ISO-10993-10:2010, Biological Evaluation of Medical Devices, Part 10: Tests for irritation and skin sensitization

IEC 62304: 2006/A1:2015 Medical device software -- Software life cycle processes

ISO 14971:2012 Medical devices -- Application of risk management to medical devices

ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements

The compliance with the Council Directive 93/42/EEC is under the monitoring of the Notified Body:

MEDCERT GmbH Pilatuspool 2 20355 Hamburg, code: 0482

Date of issue: 23 December 2020



Dmitry Novikov, President