

DECLARATION OF CONFORMITY



We,

TELEMED UAB

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

Declare under our sole responsibility that:

Equipment	Ultrasound scanners	Probes	
	<i>ArtUs EXT-1H</i>	<i>C5-2H60-A5</i>	<i>P5-1S15-A6</i>
		<i>L12-5N40-A4</i>	<i>LF9-5N60-A3</i>
		<i>L15-7H40-A5</i>	<i>LF11-5H60-A3</i>
		<i>L18-7H30-A5</i>	<i>MCV9-5N10-A3</i>
Software	<i>Echo Wave II</i>		

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: General requirements for basic safety and essential performance, 2. Collateral standard: Electromagnetic compatibility - Requirements and tests

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

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

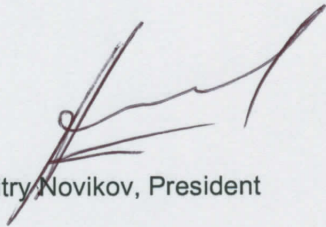
IEC 62366-1:2015 Medical devices -- Part 1: Application of usability engineering to medical devices

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: 22 February 2021


Dmitry Novikov, President