

DECLARATION OF CONFORMITY



We, **TELEMED UAB**
Dariaus ir Gireno str. 42, Vilnius, LT-02189 Lithuania

Declare under our sole responsibility that:

Equipment	Ultrasound scanners	Probes	
	<i>SmartUs EXT-1M</i>	<i>BIPL12-5L70H-4</i>	<i>L15-6L25N-4</i>
	<i>SmartUs EXT-3M</i>	<i>BIPC9-4R10H-4</i>	<i>L15-7L40H-5</i>
		<i>BIPC8-4R10N-4</i>	<i>L12-5L40N-4</i>
		<i>BIPL10-4L60N-4</i>	<i>L18-10L30H-4</i>
		<i>C5-2R60H-5</i>	<i>MCV9-5R10NI-3</i>
		<i>C5-2R60HI-5</i>	<i>P5-1L15SI-6</i>
		<i>C5-2R60NI-5</i>	<i>P8-3L10SI-6</i>
		<i>C7-3R50NI-5</i>	
Software	<i>Echo Wave II</i>		
Drivers	<i>TELEMED Drivers Package</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, Part 1: General requirements for basic safety and essential performance.

IEC 60601-1-2: 2007, Part 1: General requirements for basic safety and essential performance, 2.Collateral standard: Electromagnetic compatibility - Requirements and tests

IEC 60601-2-37:2007 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, Biological Evaluation of Medical Devices Part 5: Tests for in vitro cytotoxicity , 1999

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

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

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

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

April 6 2016

Dmitry Novikov, president