

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>ClarUs</i>	<i>MCV9-5R10N-3</i>	<i>L12-5L40N-4</i>
	<i>ClarUs EXT-1M</i>	<i>MC5-2R20N-3</i>	<i>C5-2R60N</i>
		<i>MC10-5R10N-3</i>	<i>C5-2R60N-3</i>
		<i>C7-3R50N-2</i>	<i>LV8-5L60N-2</i>
		<i>MC10-5R10N</i>	<i>MC10-5R20NI-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

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Dmitry Novikov, president