

# 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>LS64 FLT-1T</i>	<i>EC6.5/10/64D-3</i>	<i>LV6.5/60/64D-3</i>
	<i>LS64 FLT-2T</i>	<i>C3.5/20/64D</i>	<i>PV6.5/10/64D-3</i>
		<i>PV6.5/10/64D-3</i>	<i>C3.5/60/64D-3</i>
		<i>C3.5/60/64D</i>	<i>HL9.0/40/64D-3</i>
		<i>C3.5/20/64D-3</i>	
	<i>LS128 EXT-1Z</i>	<i>EC6.5/10/128Z-3</i>	<i>C3.5/60/128Z</i>
	<i>LS128 EXT-2Z</i>	<i>C3.5/20/128Z-3</i>	<i>C3.5/60/128ZI-5</i>
	<i>LS128 CEXT-1Z</i>	<i>PV6.5/10/128Z-3</i>	<i>BIPR10L60/128Z</i>
	<i>LS128 CEXT-2Z</i>	<i>C4.5/50/128Z-2</i>	<i>LV7.5/60/128Z-2</i>
		<i>HL9.0/40/128Z-4</i>	<i>HL9.0/60/128Z-2</i>
		<i>C7.5/20/128ZI-3</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