DECLARATION OF CONFORMITY

CE 0482

We, **TELEMED UAB**

Dariaus ir Gireno str. 42, Vilnius, LT-02189 Lithuania

Declare under our sole responsibility that:

Equipment	**Ultrasound scanners**	**Probes**	
	Echo Blaster 128 EXT-1Z	***EC6.5/10/128Z-3***	***C3.5/60/128Z***
	Echo Blaster 128 CEXT-1Z	***C3.5/20/128Z-3***	***HL9.0/60/128Z-2***
	Echo Blaster 128 INT-1Z	***PV6.5/10/128Z-3***	***LV7.5/60/128Z-2***
	Echo Blaster 128 INT -2Z	***C4.5/50/128Z-2***	***C3.5/60/128ZI-5***
		HL9.0/40/128Z-2	
		C7.5/20/128ZI-3	
Software	***Echo Wave II***		
Drivers	***TELEMED Drivers Package***		

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