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**	
	SmartUs EXT-1M	***BIPL12-5L70H-4***	***L15-6L25N-4***
	SmartUs EXT-3M	***BIPC9-4R10H-4***	***L15-7L40H-5***
		BIPC8-4R10N-4	***L12-5L40N-4***
		BIPL10-4L60N-4	***L18-10L30H-4***
		C5-2R60H-5	***MCV9-5R10NI-3***
		C5-2R60HI-5	***P5-1L15SI-6***
		C5-2R60NI-5	***P8-3L10SI-6***
		C7-3R50NI-5	

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

April 6 2016

Dmitry Novikov, president