DECLARATION OF CONFORMITY

CE 0482

We,

TELEMED UAB

Highway Business Centre
Savanoriu pr. 178A
Vilnius LT-03154 Lithuania

Declare under our sole responsibility that:

Equipment	**Ultrasound scanners**	**Probes**		
	SmartUs EXT-1M	*C7-3R50NI-5*	*L12-5L40N-4*	*P5-1L15SI-6*
	SmartUs EXT-3M	*C5-2R60NI-5*	*L12-5L60N-2*	*P8-3L10SI-6*
		C5-2R60HI-5	*L13-4L55H-4*	*BIPC8-4R10N-4*
		MCV9-5R10N-3	*L15-6L25N-4*	*BIPL10-4L60N-4*
		MC10-4R12N-4	*L15-7L40H-5*	*BIPC9-4R10H-4*
			L18-10L30H-4	*BIPL12-5L70H-4*
Software	*Echo Wave II*			

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/A1:2012, Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2: 2014, Part 1: General requirements for basic safety and essential performance, 2. Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-2-37:2015 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 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
ISO-10993-10:2010, Biological Evaluation of Medical Devices, Part 10: Tests for irritation and skin sensitization
IEC 62304: 2006/A1:2015 Medical device software -- Software life cycle processes
ISO 14971:2012 Medical devices -- Application of risk management to medical devices
IEC 62366-1:2015 Medical devices -- Part 1: Application of usability engineering to medical devices
ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements

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