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 scanner***	***Ultrasound Probes***	
	MicrUs EXT-1H	***L12-5N40-M3***	***MC4-2R20S-3***
		L12-5L40S-3	***MC8-4R20S-3***
		L12-5N40-M3V	***MC10-5R10S-3***
		L15-6L25S-3	***MCV9-5R10S-3***
		C5-2R60S-3	

Classification: **Class IIa** (in compliance with Annex II, Art.11 Medical Device Directive) is in conformity with:

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 60601-2-37:2015 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 Medical device software -- Software life cycle processes
ISO 14971:2012 Medical devices -- Application of risk management 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

In addition, we ensure and declare that the distributed products do not contain a medicinal substances or materials derived from animal or human tissue.

The compliance with the Council Directive MDD 93/42/EEC is under the monitoring of the Notified Body: **MEDCERT GmbH Pilatuspool 2 20355 Hamburg, code: 0482**

Vilnius, august 11, 2021

Dmitry Novikov, president