EU DECLARATION OF CONFORMITY

CE 0482

We, **TELEMED UAB**

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

Declare under our sole responsibility that:

Products:	Ultrasound scanners	***ArtUs EXT-1H, ArtUs EXT-2H***	
	Ultrasound Transducers	***C5-2H60-A5***	***LF9-5N60-A3***
		C6-1H50-A5	***LF11-5H60-A3***
		L12-5N40-A4	***MCV9-5N10-A3***
		L15-7H40-A5	***P5-1S15-A6***
		L18-7H30-A5	

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)

EN 60601-1:2006, EN 60601-1:2006/AC:2010, EN 60601-1:2006/A1:2013, EN 60601-1:2006/A1:2013/AC:2014, EN 60601-1:2006/A12:2014 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1: 2005, IEC 60601-1:2005/A1:2012)

EN 60601-1-2:2015 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests (IEC 60601-1-2:2014)

EN 60601-2-37:2008, EN 60601-2-37:2008/A11:2011, EN 60601-2-37:2008/A1:2015 Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment (IEC 60601-2-37:2007, IEC 60601-2-37:2007/AMD1:2015)

EN ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)

EN ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)

EN ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)

EN 62304:2006 Medical device software – Software life cycle processes (IEC 62304:2006)

EN ISO 14971:2019 Medical devices – Application of risk management to medical devices (ISO 14971:2019)

EN 62366-1:2015 Medical devices - Application of usability engineering to medical devices (IEC 62366-1:2015)

ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer – 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, April 1, 2022

Dmitry Novikov, President