DECLARATION OF CONFORMITY

Manufacturer	Mediq Suomi Oy Riihitontuntie 7D FIN-02200 ESPOO FINLAND
Declaration that the product:	Sinuscan ultrasound instrument, type 301, with power supply Friwo FW8002M/12 conforms to the following European Union directives and standards identified in this declaration.
Technical file:	Issued for Sinuscan 301, level 1.5
EC Product Class:	IIa
EU Directive:	93/42/EEC, Medical devices
Conformity Assessment Procedure:	Annex VI, Quality system is verified by VTT Expert Services Ltd - Notified Body no. 0537 (EC Certificate no. VTT-C-12323-01-1027-636-18)
Standards:	IEC 60601-1-2 Ed. 4.0 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance- Collateral Standard: Electromagnetic disturbances-Requirements and tests ISO 14971, Medical device* - Application of risk management to medical devices IEC 60601-1 Ed.3.1 Medical electrical equipment: Part 1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems. IEC 60601-1-2, Medical electric equipment: Part 1: General requirements for safety.2. Collateral Standard: Electromagnetic compatibility - Requirements and tests IEC 60601-2-37, Medical electrical equipment - Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment IEC 61157, Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
Signature:	25th April 2018, Espoo

Ilari Vaalavirta
Managing Director
Mediq Suomi Oy

Kari Vuorenlehto
Finance Director
Mediq Suomi Oy