DECLARATION OF CONFORMITY

Manufacturer	Mediq Suomi Oy Vuoritontunkuja 6 FIN-02200 ESPOO FINLAND SRN: FI-MF-000016267	
Declares that the product:	Sinuscan ultrasound instrument, model 301, Basic-UDI with power supply Friwo FW8002M/12 conforms to the following European Union directives and regulations and standards identified in this declaration.	
EC Product Class	IIa	
EU Directive	MDD 93/42/EEC	COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices, as amended in 2007/47/EC
Conformity Assessment Procedure	Annex VI, Quality system is verified by Eurofins Expert Services - Notified Body no. 0537 (EC Certificate no. VTT-C-12323-01-1027-636-18)	
Regulations:	Finnish law 629/2010	Laki eräistä EU-direktiiveissä säädetyistä lääkinnällisistä laitteista, Finnish MedicaL Device Act (as changed in 2021)
	Finnish law 936/2017	Laki terveydenhuollon laitteista ja tarvikkeista annetun lain muuttamisesta
	Finnish law 1482/2019	Laki terveydenhuollon laitteista ja tarvikkeista annetun lain muuttamisesta
	Finnish law 719/2021	Laki lääkinnällisistä laitteista, Finnish Medical Device Act
	Directive 2011/65/EU	RoHS directive. Restriction of the use of certain hazardous substances in electrical and electronic equipment.
	Directive 2012/19/EU	WEEE directive. Waste electrical and electronic equipment.
Standards:	EN ISO 13485:2016	Medical devices -- Quality management systems -- Requirements for regulatory purposes
	EN ISO 14971:2019	Medical devices. Application of risk management to medical devices
	IEC 62366-1:2015 + A1:2020	Medical devices – Part 1: Application of usability engineering to medical devices
	EN ISO 15223-1:2016	Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements

EN 1041:2008	Information supplied by the manufacturer of medical devices
IEC 62304:2006 + A1:2015	Medical device software - software lifecycle processes
EN 60601-1:2006 + A1:2013 (ed 3.1) IEC 60601-1:2005 + A1:2012 (ed 3.1)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
EN 60601-1-2:2015 IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6:2010 + A1:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-2-37:2007	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
MEDDEV 2.7/1 rev. 4	Clinical Evaluation: A guide to manufacturers and Notified Bodies under the MDD and the AIMDD

Signatures: 1 February, 2022

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