
	EU Declaration of Conformity for Flowmaster according to Regulation (EU) MDD 93/42/EEC	0291-DEC-008	V4.00
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Legal Manufacturer: Medical Measurement Systems B.V. Colosseum 25 7521 PV Enschede Netherlands	European Authorized Representative (if applicable): N/A
Medical Device(s)/Family:	Uroflowmeter, Flowmaster
Basic UDI-DI:	Refer to Appendix A
Declaration:	The products listed herein are under the sole responsibility of Medial Measurement Systems B.V. and are in conformity to Essential Requirements (Annex II) of Regulation (EU) MDD 93/42/EEC on Medical Devices and applicable transposed laws.
Classification:	Refer to Appendix A
Conformity Assessment Route:	EU Declaration of Conformity based on a quality management system (Annex II.3), excluding assessment of the technical documentation (Annex II.4).
Intended Use – Flowmaster:	The Flowmaster system is intended for uroflow measurements. The Flowmaster is intended to assist physicians in executing uroflowmetry investigations, analysing collected data and archiving patient and testing information.
Notified Body:	TUV Rheinland LGA Products GmbH (Notified Body #0197)
EC Certificate Number:	HD 1799860-1, Issued August 20 th , 2020
Quality Management Systems Certificate:	Certificate Number: SX 1799860-1
Place and Date of Issue:	Nürnberg, Germany; August 20 th , 2020

This EU declaration of conformity is issued under the sole responsibility of Medical Measurement Systems B.V.

Signature:

Date: 2021-04-15:



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Appendix 1: Declaration of Conformity Product List

Systems						
Catalogue Number	Product Name	EC Certificate Number	Group on EC Certificate	EU Risk Class	EU Rule	UDI-DI
U1-1	Flowmaster	HD 1799860-1	Uroflowmeter	Im	12	08717775954828

Modules						
Catalogue Number	Product Name	EC Certificate Number	Group on EC Certificate	EU Risk Class	EU Rule	UDI-DI
Flowsensor3	Flowsensor	HD 1799860-1	Uroflowmeter	Ila	10	08717775955627
Flowsensor3-BT	Flowsensor Bluetooth	HD 1799860-1	Uroflowmeter	Ila	10	08717775955634

Signature:

Date: 2021-04-15:

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