DECLARATION OF CONFORMITY

Manufacturer's Name: Maxtec, LLC
Address: 2305 South 1070 West
Salt Lake City, Utah 84119
USA

SRN: US-MF-000003961

European Representative: EMERGO EUROPE
Westervoortsedijk 60,
6827 AT Arnhem
The Netherlands

European Representative SRN: NL-AR-000000116

Basic UDI DI: 081777002THORPEFM6E

Product Name(s): Thorpe Flowmeter Family

Part Number/ Identification	
R302P01	RP34P03-105
R302P06	RP34P03-106
R302P08	RP34P03-108
R303P01	RP34P03-109
R305P01	RP34P03-116
R305P08	RP34P03-118
R305P09	RP34P03-121
R306P01	RP34P03-122
R306P02	RP34P03-126
R306P05	RP34P03-202
R306P06	1MFA1002AUMX
RP34P01-002	1MFA1002AUMX-L
RP34P03-001	1MFA1002CIMX
RP34P03-002	1MFA1002CIMX-L
RP34P03-003	1MFA1002CIMX-R
RP34P03-004	1MFA10DNCIMX
RP34P03-006	1MFA3002AUMX
RP34P03-008	1MFA3002CIMX-L
RP34P03-009	1MFA3002CIMX-R
RP34P03-101	1MFA35BOCAUMX

4MFA1002AUMX-L	1MFA8001AUMX
4MFA1002CIMX	1MFA8002AUMX
4MFA1002CIMX-L	1MFA8002CIMX
4MFA10BOCAUMX	1MFA9001AUMX
6MFA1001AUMX	4MFA1001AUMX
8MFA10BOCAUMX	Y8MFA10BOCAUMX
Y1MFA1001CIMX	

Intended Purpose:	Flowmeters are intended for use by physicians, respiratory therapists, and other authorized hospital personnel to administer selected doses of medical oxygen or air to a patient.	
GMDN:	61365 – Medical Gas Flowmeter, Thorpe Tube	
Class & Classification Criteria:	Class IIa	Clause 3.2 Rule 11 of Annex IX of MDD
	Class IIa	Clause 4.2 Rule 2 of Annex VIII MDR 2017/745

This EU declaration of conformity is issued under the sole responsibility of the manufacturer. We herewith declare that the above mentioned products meet the provisions of the following EC Council Regulations, Common Specifications and Standards. All supporting documents are retained under the premises of the manufacturer and the European Representative.

Regulations:	General Application Directives: Medical Device Directive, Council Directive 93/42/EEC of 14 June 1993 per Annex II Excluding Section 4 as amended by 2007/47/EC of September 2007
Notified Body:	TÜV SÜD Product Service RIDLERSTRASSE 65, D-80339 MUNICH, Germany Number 0123
Conformity Assessment:	Full Quality Assurance per Annex II MDD 93/42/EEC Excluding Section 4
EC Certificate No.:	G1 045041 00 25 Rev. 00
Date CE mark was affixed:	26 August 2016
Extension Confirmation Letter:	CL 045041 0026

This Declaration is considered valid from the date of the signature below until December 31, 2028.

Issued by Signature: Ashwini Kadam Digitally signed by Ashwini Kadam Date: 2026.10.07 13:13:13 +05'30' Date: 07/10/2026

Name: Ashwini Kadam
Position: Regulatory Specialist
Place of Issue: Salt Lake City, Utah, USA 84119

Approved by Signature: Rebecca Hudson Rebecca Hudson (Oct 8, 2026 14:17:16 EDT) Date: Oct 8, 2026
Name: Rebecca Hudson
Position: VP, Regulatory Affairs and Quality Assurance

This Declaration supersedes any preceding Declaration of Conformity for the Thorpe Tube Flowmeter Family.

Applied Common Specifications and Standards

The referenced list of Common Specifications and harmonized standards for which documented evidence of compliance can be provided includes:

EN ISO 13485:2016 (ISO 13485:2016)
EN ISO 14971:2019
EN ISO 20417:2021
EN ISO 15223-1:2021
IEC 62366-1:2015
EN ISO 10993-1:2025
EN ISO 15001:2011 (ISO 15001:2010)
EN ISO 15002:2023
ISO 18562-1:2024
ISO 18526-3:2024
ISO 18526-2:2024

QR-0030 (13) THORPE TUBE FLOWMETER

Final Audit Report 2026-10-08

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