

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 Tube Flowmeter Family (0-200 cc, 0-1 LPM, 0-3.5 LPM, 0-3 LPM, 0-5 LPM, 0-8 LPM, 0-15 LPM, 2-26 LPM, 0-30 LPM, 0-70 LPM)
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.
Risk Class & GMDN:	Class IIa 61365 – Medical Gas Flowmeter, Thorpe Tube
Classification Criteria:	Clause 3.2 Rule 11 of Annex IX of MDD
<p>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.</p>	
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

This Declaration is considered valid from the date of the signature below until May 26, 2024

Issued by Signature:  Date: May 08, 2023

Name: Anvitha Anand Rao
Position: Regulatory and Quality Product Engineering Specialist

Approved by Signature:  Date: May 08, 2023

Name: Sidra Hankins
Position: VP of QA/RA

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

Applied Common Specification 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 14971:2012 (ISO 14971:2017, Corrected version 2007-10-01)
EN ISO 20417:2021
EN ISO 15223-1:2021
EN ISO 10993-1:2009 (ISO 10993-1:2009)
EN ISO 15001:2011 (ISO 15001:2010)
EN ISO 15002:2008 (ISO 15002:2008)
ISO 18562-1:2017
ISO 18526-3:2017
ISO 18526-2:2017