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: 081777002FLOWMETERMANIHN

Product Name(s): Flowmeter Manifold (R220 Series)

Part Number/ Identification	
R220P01-001	R220P07-005
R220P01-002	R220P10-001
R220P01-008	R220P11-001
R220P01-009	R220P63-101
R220P01-013	R220P63-102
R220P01-014	R220P64-101
R220P01-015	R220P64-102
R220P01-109	R220P64-103
R220P01-111	R220P64-104
R220P01-112	R220P64-201
R220P01-113	R220P87-001
R220P01-114	R220P87-002
R220P01-115	R220P87-201
R220P01-201	R220P88-001
R220P03-001	R220P10-007
R220P07-001	R220P10-009
R220P89-001	R220P89-002

Intended Purpose:	The Flowmeter Manifold is intended for use where a flow of metered gas is required and to allow the gas to be delivered through one or two flowmeters that are connected to a standard IV pole up to 1.5” outer diameter.
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:	25 February 2015
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 13:19:28 +05'30' Date: 07/10/2026

Name: Ashwini Kadam
Position: Regulatory Specialist

Approved by Signature: Rebecca Hudson
Rebecca Hudson (Oct 8, 2026 14:12:49 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 Flowmeter Manifold.

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

QR-0042 (11) FLOWMETER MANIFOLD

Final Audit Report 2026-10-08

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