



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
Westervoorsedijk 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 | R220P11-001 |
| R220P01-002 | R220P11-005 |
| R220P01-008 | R220P15-001 |
| 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 | R220P64-105 |
| R220P01-113 | R220P64-201 |
| R220P01-114 | R220P87-001 |
| R220P01-115 | R220P87-002 |
| R220P01-201 | R220P87-201 |
| R220P03-001 | R220P88-001 |
| R220P07-001 | R220P10-002 |
| R220P07-005 | R220P10-007 |
| R220P10-001 | R220P10-009 |

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: _____ Date: January 16, 2025

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

Approved by Signature: _____ Date: 16 January 2025

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 10993-1:2018

ISO 18562-1:2017

ISO 18562-2:2017

ISO 18562-3:2017

ISO 20417:2021

EN ISO 15001:2011 (ISO 15001:2010)

EN ISO 15002:2008 (ISO 15002:2008)