

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
Prinsessegracht 20
2515 AP The Hague
The Netherlands

Basic UDI DI: Pending Assignment

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

Intended Purpose: 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.

Risk Class & GMDN: Class IIa 61365 – Medical Gas Flowmeter, Thorpe Tube

Classification Criteria: Clause 3.2 Rule 11 of Annex IX of MDD

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

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

Signature:  Date: 10/9/2021

Name: Sidra Hankins
Position: VP of QA/RA

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 14971:2007, Corrected version 2007-10-01)
EN 1041:2008
EN ISO 15223-1:2016 (ISO 15223-1:2016, Corrected version 2017-03)
EN ISO 10993-1:2009 (ISO 10993-1:2009)
EN ISO 15001:2011 (ISO 15001:2010)
EN ISO 15002:2008 (ISO 15002:2008)