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** (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)

Part Number/ Identification	
R302P01	RP34P03-105
R302P02	RP34P03-106
R302P04	RP34P03-108
R302P06	RP34P03-109
R302P08	RP34P03-116
R303P01	RP34P03-118
R303P04	RP34P03-121
R303P06	RP34P03-122
R304P01	RP34P03-126
R304P06	RP34P03-202
R304P09	1MFA1002AUMX
R305P01	1MFA1002AUMX-L
R305P04	1MFA1002AUMX-R
R305P06	1MFA1002CIMX
R305P08	1MFA1002CIMX-L
R305P09	1MFA1002CIMX-R
R306P01	1MFA10DNCIMX
R306P02	1MFA3002AUMX
R306P04	1MFA3002CIMX-L

R306P05	1MFA3002CIMX-R
R306P06	1MFA35BOCAUMX
R306P07	1MFA8001AUMX
RP34P01-002	1MFA8002AUMX
RP34P03-001	1MFA8002CIMX
RP34P03-002	1MFA9001AUMX
RP34P03-003	4MFA1001AUMX
RP34P03-004	4MFA1001CIMX
RP34P03-005	4MFA1002AUMX-L
RP34P03-006	4MFA1002CIMX
RP34P03-008	4MFA1002CIMX-L
RP34P03-009	4MFA10BOCAUMX
RP34P03-101	6MFA1001AUMX
RP34P03-102	8MFA10BOCAUMX
RP34P03-103	Y1MFA1001CIMX
RP34P03-104	Y8MFA10BOCAUMX

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: _____ Date: 14 November 2024

Name: Sri Divya Kadiyala
Position: Regulatory and Quality Systems Compliance Specialist
Place of Issue: Salt Lake City, Utah, USA 84119

Approved by Signature: Rebecca Hudson Digitally signed by Rebecca Hudson DN: cn=Rebecca Hudson, o=PermaPure/Maxtec, ou=VP, RA/QA, email=rhudson@permapure.com, c=US Date: 2024.11.14 16:42:14 -05'00' Date: 14 November 2024
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 14971:2012 (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
IS0 18526-2:2017