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: 081777002MAXVENTURIFV

Product Name(s): MaxVenturi Family (MaxVenturi, Venturi Muffler)

Part Number/ Identification
R211P03-019
R211P03-020
R211P03-022
R211P03-025
R211P03-033
R211P03-036
R211P03-124
R211P38
R211P38-001

Intended Purpose: The MaxVenturi Series is intended for use in high-flow oxygen therapy applications where the ability to deliver diluted oxygen to the breathing gas pathway is required. Oxygen being delivered from this device is for adult patients. It is a restricted medical device intended for use by qualified, trained personnel, under the direction of a physician, in professional health care settings, i.e., hospital, sub-acute institutions, home care, and intra-hospital transport.

The MaxVenturi is not a life supporting device.

GMDN:	44225 – Oxygen/air breathing gas mixer, hospital
Risk Class & Classification Criteria:	Class IIa Clause 3.2 Rule 10 of Annex IX of MDD Class IIa Clause 6.4 Rule 12 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 RoHs (EU) 2015/863
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
Extension Confirmation Letter:	CL 045041 0026
Date CE mark was affixed:	10 October 2007

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 12:59:22 +05'30' Date: 17/10/2026

Name: Ashwini Kadam
Position: Regulatory Specialist

Approved by Signature: Rebecca Hudson Rebecca Hudson (Oct 8, 2026 14:21:29 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 MaxVenturi 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 14971:2019 (ISO 14971:2019)
EN ISO 20417:2021
ISO 15223-1:2021
ISO 18562-1:2024
ISO 18562-2:2024
ISO 18562-3:2024
ISO 10993-1:2025
IEC 60601-1:2005+AMD1:2012+AMD2:2020
EN IEC 62304:2006/AMD1:2015/AC:2008
ISO 80601-2-55:2018
IEC 60601-1-2:2014/AMD1:2020
IEC 60601-1-6:2010/AMD1:2013/AMD2:2020
IEC 62366-1:2015/Amd 1:2020
IEC 60601-1-11:2015 + AMD1:2020
IEC 60601-1-12:2014 + AMD1:2020

QR-0004 (25) MaxVenturi

Final Audit Report 2026-10-08

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