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DECLARATION OF CONFORMITY

Manufacturer's Name: Address:	Maxtec, LLC 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)
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.*
Risk Class & GMDN:	Class IIa 44225 – Oxygen/air breathing gas mixer, hospital
Classification Criteria:	Clause 3.2 Rule 10 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 RoHs (EU) 2015/863

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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:	10 October 2007

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

Issued by Signature: _____ Date: May 08, 2023

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

Approved by Signature: _____ Date: May 08, 2023

Name: Sidra Hankins
Position: VP of QA/RA

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