

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
2514 AP The Hague
The Netherlands

European Representative SRN: NL-AR-000000116

Basic UDI DI: Pending Assignment

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

Intended Purpose: The MaxVenturi is intended to deliver diluted oxygen in high-flow oxygen therapy applications. The Venturi Muffler is intended for use in conjunction with the MaxVenturi to decrease noise generated by the MaxVenturi.

Risk Class & GMDN: Class IIa 44225 - Oxygen/air breathing gas mixer, hospital

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: 10 October 2007

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

Signature: _____ Date: December 5, 2021

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)
BS EN ISO 14971:2019 (ISO 14971:2019)
BS EN ISO 20417:2021
ISO 15223-1:2021