

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: 0853061006MICROMAXMW

Product Name(s): MicroMax Air-Oxygen Blender

Intended Purpose: The MicroMax Air-Oxygen Blender is intended to dispense a continuous and precise blend of medical air and USP oxygen via outlet ports to infant, pediatric, and adult patients. The exact Fractional Concentration of Inspired Oxygen (FiO₂) blend of gases corresponds to the dialed in FiO₂ setting indicated by the control knob (dial).

(This is not intended as a life supporting device)

Risk Class & GMDN: Class IIb 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: 15 August 2012

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 MicroMax Air Oxygen Blender 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 15223-1:2021
EN ISO 20417:2021
IEC 60601-1-6:2010/AMD1:2013



SENSING. ANALYSIS. DELIVERY.

ISO 18562-2:2017
ISO 18562-3:2017