



## 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

Part Number/ Identification	
R203P13	R203P14
R203P13-001	R203P14-001
R203P13-002	R203P14-008
R203P13-003	R203P14-009
R203P13-008	

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)*

GMDN: 44225 – Oxygen/Air Breathing Gas Mixer, Hospital

Class & Classification Criteria: Class IIb      Clause 3.2 Rule 11 of Annex IX of MDD  
Class IIb      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

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

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: 28 October 2024

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

Approved by Signature: \_\_\_\_\_ Date: 28 October 2024

Name: Rebecca Hudson  
Position: VP, Regulatory Affairs and Quality Assurance

This Declaration supersedes any preceding Declaration of Conformity for the MicroMax Air Oxygen Blender 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 14971:2019 (ISO 14971:2019)  
EN ISO 15223-1:2021  
EN ISO 20417:2021  
IEC 60601-1-6:2010/AMD1:2013  
ISO 18562-2:2017  
ISO 18562-3:2017