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	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: Ashwini Kadam Digitally signed by Ashwini Kadam Date: 2026.10.07 13:14:43 +05'30' Date: 07/10/2026

Name: Ashwini Kadam
Position: Regulatory Specialist

Approved by Signature: Rebecca Hudson Rebecca Hudson (Oct 8, 2026 14:16:24 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 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)
ISO 20417:2021
IEC 60601-1-6:2010 +A1:2013+A2:2020
EN 62366-1:2015 + AC: 2015 +A1:2020
ISO 10993-1:2025
ISO 11195:2018
ISO 18562-1:2024
ISO 18562-2:2024
ISO 18562-3:2024
ISO 15001:2010
EN ISO 15223-1:2021
ISTA 2A (2011)

QR-0034 (17) MicroMax

Final Audit Report 2026-10-08

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