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: 081777002ULTRAMAXO2K8

Product Name(s): UltraMaxO2 Oxygen Analyzer

Part Number/ Identification
R221P11
R221P11-001

Intended Purpose: The UltraMaxO2 Oxygen Analyzer is a tool intended to measure oxygen purity, flow, and pressure of an oxygen concentrator.

Risk Class & GMDN: Class I 46049 – Respiratory Oxygen Monitor, Battery Powered

Classification Criteria: Clause 6.5 Rule 13 of Annex VIII EU 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: Medical Device Regulation 2017/745

Notified Body: N/A

Conformity Assessment:	Annex II Technical Documentation & Annex III, Technical documentation on Post-Market Surveillance
EC Certificate No.:	Product is Self-certified
Date CE mark was affixed:	15 December 2011

This Declaration is considered valid from the date of the signature below.

Issued by Signature: Ashwini Kadam Digitally signed by Ashwini Kadam Date: 2026.10.07 14:40:53 +05'30' Date: 07/10/2026

Name: Ashwini Kadam
Position: Regulatory Specialist

Approved by Signature: Rebecca Hudson Rebecca Hudson (Oct 8, 2026 14:22:05 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 UltraMaxO2 Oxygen Analyzer.

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
EN ISO 20417:2021
ISO 15223-1:2021
IEC 60601-1:2005 + AMD1:2012/AMD2:2020
IEC 60601-1-6:2010 + AMD1:2013/ AMD2:2020
IEC 62304:2006 + AMD1:2015
IEC 62366-1:2015
IEC 60601-1-2:2014 + A1:2020
IEC 60601-1-11:2015 + AMD1:2020

QR-0003 (12) UltraMaxO2

Final Audit Report 2026-10-08

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