

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
R221P11-004

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: _____ Date: 23 January 2025

Name: Anvitha Anand Rao

Position: Regulatory and Quality Product Engineering Specialist

Approved by Signature: _____ Date: Jan 27, 2025

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