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DECLARATION OF CONFORMITY

Manufacturer's Name: Address:	Maxtec, LLC 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
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 6.2 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

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EC Certificate No.: Product is Self-Certified

Date CE mark was affixed: 15 December 2011

Issued by Signature: _____ Date: 18 June, 2024

Name: Sri Divya Kadiyala
Position: Regulatory and Quality Systems Compliance Specialist

This Declaration supersedes any preceding Declaration of Conformity for the UltraMaxO2.

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
EN ISO 20417:2021
ISO 15223-1:2021