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: 0081777002MAXO2UA
0085306100MAXO2UA

Product Name(s): MaxO2+ Series Oxygen Analyzers
(MaxO2+A – R217P62 series, MaxO2+AE - R217P72 series, Handi+ - R218P12 series)

Part Number/ Identification (under each Basic UDI)	
0081777002MAXO2UA	**0085306100MAXO2UA**
R217P62-002	R217P62
R217P62-006	R217P72
R217P62-008	
R217P72-003	
R217P72-005	
R218P12	
R218P12-001	
R218P12-012	

Intended Purpose: The MaxO2+ oxygen analyzers are intended as tools for use by qualified personnel to spot-check or measure oxygen concentration air/oxygen mixtures being delivered to patients ranging from newborns to adults. It can be used in pre-hospital, hospital, and sub-acute settings. The MaxO2+ oxygen analyzers are not a life supporting device.

maxtec

SENSING. ANALYSIS. DELIVERY.

GMDN:	35219 – Analyzer, Gas, Oxygen	
Class & Classification Criteria:	Class IIa	Clause 3.2 Rule 10 of Annex IX of MDD
	Class IIa	Clause 6.2 Rule 10 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 Regulation (EU) 2023/1542 Of The European Parliament And Of The Council of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC
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:	21 June 2004 (MaxO2+) and 03 December 1998 (Handi+)
Extension Confirmation Letter:	CL 045041 0026

This declaration is considered valid from the date of signature below until December 31, 2028.

Signature: _____ Date: 17 December 2024

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

Approved by Signature: Rebecca Hudson Digitally signed by Rebecca Hudson DN: cn=Rebecca Hudson, o=PermaPure/Maxtec, ou=VP, RA/QA, email=rhudson@permapure.com, c=US Date: 2024.12.18 14:31:42 -05'00' Date: 18 December 2024
Name: Rebecca Hudson
Position: VP, Regulatory Affairs and Quality Assurance

This Declaration supersedes any preceding Declaration of Conformity for the MaxO2+ Series Family of Oxygen Analyzers.

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 1041:2008
EN ISO 10993-1:2009
EN 62366:2008
EN ISO 15223-1:2016 (ISO 15223-1:2016, Corrected version 2017-03)
IEC 60601-1:2005 (EN 60601-1:2006/ AC:2010)
IEC 60601-1-2:2004 (EN 60601-1-2:2004)
ISO 80601-2-55:2011