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: 0853061006MAXO2ME76

Product Name(s): MaxO2ME

Part Number/ Identification
R230P01
R230P01-001
R230P01-002

Intended Purpose: The MaxO2 ME oxygen monitor is intended for continuous monitoring of the concentration of oxygen being delivered to patients ranging from newborns to adults. It can be used in the hospital and sub-acute settings.

The MaxO2 ME is not a life supporting device.

GMDN: 35219 – Analyzer, Gas, Oxygen

Class & Classification Criteria:	Class IIb	Clause 3.1 Rule 9 of Annex IX of MDD
	Class IIb	Clause 6.1 Rule 9 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 RoHs (EU) 2015/863
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:	14 May 2016
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: _____ Date: 28 October 2024

Name: Sri Divya Kadiyala
Position: Regulatory and Quality Systems Compliance Specialist
Place of Issue: Salt Lake City, Utah 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: 2024.10.28 19:15:42 -04'00' Date: 28 October 2024
Name: Rebecca Hudson
Position: VP, Regulatory Affairs and Quality Assurance

This Declaration supersedes any preceding Declaration of Conformity for the MaxO2ME 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)
EN ISO 20417:2021
ISO 15223-1:2021
EN 60601-1:2006/A1:2013 (IEC 60601-1:2005/A1:2012)
ISO 80601-2-55:2011
EN ISO 10993-1:2009 (ISO 10993-1:2009)
IEC 60601-1-8:2006/AMD1:2012
ISTA 2A (2011)
EN 60601-1-2:2015 (IEC 60601-1-2:2014)
EN 62304:2006