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: 0081777002MAXBLENDTW
0085306100MAXBLENDTW

Product Name(s): MaxBlend Family
(MaxBlend2 R229P01, R229P02 series, MaxBlend Lite R229P03 series) ,
Blender Maintenance kit

Part Number/ Identification (under each Basic UDI)	
0081777002MAXBLENDTW	**0085306100MAXBLENDTW**
R229P01-004	R229P01-001
R229P01-010	R229P01-007
R229P01-011	R229P02-001
R229P01-020	R229P02-004
R229P01-024	R229P02-007
R229P01-025	R229P03-001
R229P01-027	R229P03-002
R229P01-028	R229P03-003
R229P01-030	R229P03-004
R229P01-031	
R229P02-010	
R229P02-101	
R229P03-005	
R229P03-006	
R229P03-007	

R229P03-008	
10003V2	

Intended Purpose: The MaxBlend2 and MaxBlend Lite is designed to provide a continuous air/oxygen gas mixture and to continuously monitor the concentration of oxygen being delivered to infant, pediatric, and adult patients. It is a restricted medical device intended for use by qualified, trained personnel, under the direction of a physician, in professional healthcare settings, i.e., hospital, subacute, and nursing-care facilities where the delivery and monitoring of air/oxygen mixtures is required. *(This is not intended as a life supporting device)*

GMDN: Class IIb 44225 – Oxygen/Air Breathing Gas Mixer, Hospital

Class & Classification Criteria:

Class IIb	Clause 3.1 Rule 9 of Annex IX of MDD
Class IIb	Clause 6.4 Rule 12 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

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: 13 September 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: Anvitha AnandRao Digitally signed by Anvitha AnandRao Date: 2025.03.04 11:13:20 -06'00' Date: 04 March 2025

Name: Anvitha Anand Rao
Position: Regulatory and Quality Product Engineering Specialist

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: 2025.03.04 13:06:43 -05'00' Date: 04 March 2025
Name: Rebecca Hudson
Position: VP, Regulatory Affairs and Quality Assurance

This Declaration supersedes any preceding Declaration of Conformity for the MaxBlend 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 15223-1:2021
EN ISO 15001:2010 (ISO 15001:2010)
EN ISO 18562-1:2020 (ISO 18562-1:2017)
EN ISO 18562-2:2020 (ISO 18562-2:2017)
EN ISO 18562-3:2020 (ISO 18562-3:2017)