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:	081777002MAXSENWA2D
Product Name(s):	Max Weak Acid Oxygen sensor

Part Number/ Identification	
R107P20	R125P03-002
R125P07	R125P11
R140P02	R125P11-001
R140P02-001	R125P95
R140P08	R140P11
R140P07-001	R125P97
R140P07-003	R140P12
R140P07-002	R125P18-003
R125P01-002	R125P18-010
R125P01-007	R125P18-004
R125P01-009	R125P18-009
R125P02-011	R125P18-012
R125P02-024	R125P18-013
R125P03-020	R140P18
R125P04-001	R125P10

Intended Purpose: Weak Acid Oxygen Sensor Family are intended to measure oxygen concentration when used in conjunction with an analytical device that can interpret the output voltage of the sensor into usable data. Common devices

	that utilize Maxtec weak acid oxygen sensors are Oxygen analyzers and monitors, mixer and blenders and anesthesia monitoring equipment.	
GMDN:	13538 – Sensor, Oxygen	
Class & Classification Criteria:	Class IIa	Clause 1.2 Rule 2 of Annex IX of MDD
	Class IIa	Clause 4.2 Rule 2 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 AnnexII MDD 93/42/EEC Excluding Section 4
EC Certificate No.:	G1 045041 00 25 Rev. 00
Date CE mark was affixed:	15 April 2000
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: Ashwini Kadam Digitally signed by Ashwini Kadam Date: 2026.10.07 12:54:57 +05'30' Date: 07/10/2026

Name: Ashwini Kadam
Position: Regulatory Specialist
Place of Issue: Salt Lake City, Utah 84119

Approved by Signature: Rebecca Hudson Rebecca Hudson (Oct 8, 2026 14:22:33 EDT) Date: Oct 8, 2026
Name: Rebecca Hudson
Position: VP, Regulatory Affairs and Quality Assurance

This Declaration supersedes any preceding Declaration of Conformity for the Weak Acid Oxygen Sensors.

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
EN ISO 10993-1:2025
IEC 60601-1-6:2010/AMD1:2013/AMD2:2020
IEC 62366-1:2015/Amd 1:2020
ISO 18562-1:2024
ISO 18562-2:2024
ISO 18562-3:2024
ISO 80601-2-55:2018

QR-0002 (24) Weak Acid Oxygen Sensor

Final Audit Report 2026-10-08

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