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:	081777002MAXSENKOHK3
Product Name(s):	KOH Oxygen Sensors

Part Number/ Identification	
R109P02-001	R113P90
R109P07	R113P90-001
R109P09	R114P70
R109P11	R114P70-006
R109P13	R114P73
R109P21	R114P75
R109P21-001	R114P80
R109P45	R115P01
R109P48	R115P01-001
R109P53	R115P03-001
R112P10	R115P03-002
R112P10-002	R115P10
R112P18	R115P10-013
R113P06	R115P63
R113P10	R116P60
R113P10-001	R116P80
R113P10-002	R116P80-003

R113P10-003	R116P82-001
R115P85	R116P10
R116P06	R113P10-901
	R113P11

Intended Purpose:	The KOH Oxygen Sensors 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. Analytical devices include, but are not limited to, oxygen analyzers, oxygen monitors, blenders, mixers, and anesthesia monitoring equipment.
GMDN:	13538 – Sensor, Oxygen
Risk 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 Annex II MDD 93/42/EEC Excluding Section 4
EC Certificate No.:	G1 045041 00 25 Rev. 00
Extension Confirmation Letter:	CL 045041 0026
Date CE mark was affixed:	14 April 2010

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 13:10:21 +05'30' Date: 07/10/2026

Name: Ashwini Kadam
Position: Regulatory Specialist

Approved by Signature: Rebecca Hudson Rebecca Hudson (Oct 8, 2026 14:18:10 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 KOH Oxygen Sensors.

Applied Common Specification 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
EN 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-0028 (13) KOH Sensors

Final Audit Report 2026-10-08

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