

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): Oxygen Sensors (Max-10, Max-108A)

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.

Risk Class & GMDN: Class IIa 13538 – Sensor, Oxygen

Classification Criteria: Clause 1.2 Rule 2 of Annex IX of MDD

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: 14 April 2010

This Declaration is considered valid from the date of the signature below until May 26, 2024

Signature:  Date: 16 January 2024

Name: Sri Divya Kadiyala

Position: Regulatory and Quality Systems Compliance Specialist

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 14971:2012 (ISO 14971:2017, Corrected version 2007-10-01)

EN ISO 20417:2021

EN ISO 15223-1:2021