

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: 081777002MAXO2UA

Product Name(s): MaxO2+ Series Oxygen Analyzers (MaxO2+A, MaxO2+AE, Handi+)

Intended Purpose: The MaxO2+ oxygen analyzers are intended as tools for use by qualified personnel to spot-check or measure oxygen concentration air/oxygen mixtures being delivered to patients ranging from newborns to adults. It can be used in pre-hospital, hospital, and sub-acute settings. The MaxO2+ oxygen analyzers are not a life supporting device.

Risk Class & GMDN: Class IIa 35219 – Analyzer, Gas, Oxygen

Classification Criteria: Clause 3.2 Rule 10 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: 21 June 2004 (MaxO2+) and 03 December 1998 (Handi+)

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

Issued by Signature:  Date: May 08, 2023

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

Approved by Signature:  Date: May 08, 2023

Name: Sidra Hankins
Position: VP of QA/RA

This Declaration supersedes any preceding Declaration of Conformity for the MaxO2+ Series Family of Oxygen Analyzers.

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 14971:2007, Corrected version 2007-10-01)
EN 1041:2008
EN ISO 10993-1:2009
EN 62366:2008
EN ISO 15223-1:2016 (ISO 15223-1:2016, Corrected version 2017-03)
IEC 60601-1:2005 (EN 60601-1:2006/ AC:2010)
IEC 60601-1-2:2004 (EN 60601-1-2:2004)
ISO 80601-2-55:2011