



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
Prinsessegracht 20
2514 AP The Hague
The Netherlands

European Representative SRN: NL-AR-000000116

Basic UDI DI: 0853061006MAXO2ME76

Product Name(s): MaxO2ME

Intended Purpose: The MaxO2ME oxygen monitor is intended for continuous monitoring of the concentration of oxygen being delivered to patients.

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

Classification Criteria: Clause 3.1 Rule 9 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

RoHs (EU) 2015/863

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

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

Signature:  Date: 10/6/2022

Name: Sidra Hankins
Position: VP of QA/RA

This Declaration supersedes any preceding Declaration of Conformity for the MaxO2ME Family.

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 (ISO 14971:2019)
- EN ISO 20417:2021
- ISO 15223-1:2021
- EN 60601-1:2006/A1:2013 (IEC 60601-1:2005/A1:2012)
- ISO 80601-2-55:2011
- EN ISO 10993-1:2009 (ISO 10993-1:2009)
- IEC 60601-1-8:2006/AMD1:2012
- ISTA 2A (2011)
- EN 60601-1-2:2015 (IEC 60601-1-2:2014)
- EN 62304:2006