



## 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  
2515 AP The Hague  
The Netherlands

Basic UDI DI: Pending Assignment

Product Name(s): Blend Up Kit - MaxO2ME Oxygen Monitor w/ Blender Manifold

Intended Purpose: The Blend Up is intended for use with low and high flow blenders. The Blend Up allows a user to securely attach a MaxO2 ME to a blender via one bracket, and an oxygen sensor via one toggled aluminum manifold. The sensor is connected to the MaxO2 ME which verifies the FiO2 produced by the blender and has alarm functions.

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

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: 3 December 1998

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

Signature:  \_\_\_\_\_ Date: May 25, 2021

Name: Sidra Hankins  
Position: VP of QA/RA

This Declaration supersedes any preceding Declaration of Conformity for the Blend Up Kit

#### Applied Common Specification and Standards

The referenced list of Common Specifications and harmonized standards for which documented evidence of compliance can be provided includes:

- ISO 80601-2-55:2011
- EN ISO 14971:2012
- IEC 60601-1:2005
- IEC 60601-1-2:2014
- CAN/CSA C22.2 NO. 60601-1:14
- EN 62366:2008
- EN 1041:2008
- ISO 15223-1:2016
- EN ISO 10993-1:2009
- ISTA 2A
- EN 50581:2012
- IEC 60601-1-8:2006
- EN 980:2008