

## 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): BlenderBuddy Family (BlenderBuddy, BlenderBuddy2)

Intended Purpose: The BlenderBuddy and BlenderBuddy2 are intended for use in conjunction with a variety of air/oxygen blenders.

Risk Class & GMDN: Class IIa 36327 – Mixer, Gas Breathing (Accessory)

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

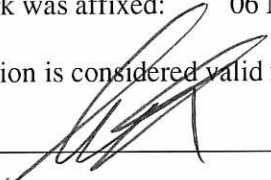
Notified Body: TÜV SÜD Product Service  
RIDLERSTRASSE 65, D-80339 MUNICH, Germany  
Number 0123

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: 06 May 2009

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

Signature:  Date: 5/25/2021

Name: Sidra Hankins

Position: VP of QA/RA

#### 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 13485:2012

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

EN 1041:2008

EN ISO 15223-1:2016

EN ISO 10993-1:2009 (ISO 10993-1:2009)