

## DECLARATION OF CONFORMITY

Manufacturer's Name: Maxtec  
Address: 2305 South 1070 West  
Salt Lake City, Utah 84119  
USA

European Representative: QNET BV  
Kantstraat 19  
NL-5076 NP Haaren  
The Netherlands

Product: Air Oxygen Blender

Model(s): MicroMax Low Flow & MicroMax High Flow (Including Pole Mount  
Bracket Accessory R100P26, RP05P07, and RP05P09)

Classification & GMDN: Class IIb Mixer, Gas, Breathing 36327

Classification Criteria: Clause 3.2 Rule 11 of Annex IX of MDD

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documents are retained under the premises of the manufacturer and the European Representative.


Directives: General application directives: Medical Device Directive, COUNCIL DIRECTIVE  
93/42/EEC of 14 June 1993 per Annex II as amended by 2007/47/EC of 5 September 2007

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

EC Certificate No.: G1 16 10 45041 020

Date CE mark was affixed: August 15, 2012

This declaration is considered valid from May 2, 2019 to December 18, 2021.

Signature:   
Name: Tammy Lavery  
Position: Director of Regulatory and Quality

Date: May 2 2019

### Applied Standards

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

EN ISO 14971-2012  
EN 1041:2008  
EN ISO 11195:1995  
EN ISO 15001:2004