

## 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: Oxygen Dilutor

Model(s): MaxVenturi

Classification & GMDN: Ila Mixer, Gas Breathing 36327

Classification criteria: Clause 3.2 Rule 10 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.

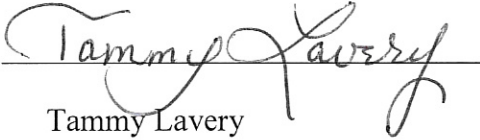
Directives: General application directives: Medical Device Directive, COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 per Annex II as amended by 2007/47/EC of 5 September 2007

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: 10 October 2007

This declaration is considered valid from November 1, 2018 to December, 18, 2021.

Signature:  Date: 11/01/2018

Name: Tammy Lavery  
Position: Director of Regulatory and Quality

## Applied Standards

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

EN ISO 14971:2012  
EN 62366:2008  
EN 1041:2008  
ISO 15223-1:2016  
ISO 13485:2012  
ISO 10993-1:2009