



premier o2 solutions

## DECLARATION OF CONFORMITY

**Manufacturer's Name:** Maxtec  
**Address:** 6526 South Cottonwood Street  
Salt Lake City, Utah 84107  
USA

**European Representative:** QNET BV  
Hommerterweg 286  
6436 AM Amstenrade  
The Netherlands

**Product:** Oxygen Dilutor

**Model(s):** MaxVenturi and OptiVenturi

**Classification & GMDN:** IIa Mixer, Breathing, Gas - 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

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

**EC Certificate No.:** G1 11 09 45041 012

**Date CE mark was affixed:** 10 October 2007

This declaration is considered valid from December 19, 2011 to December 18, 2016.

**Signature:** Tammy Lavery **Date:** Dec 19, 2011

**Name:** Tammy Lavery, RAC  
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SECTION 13 REV H  
RF192 REV B