



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 Sensor

Model(s): MAX-1, MAX-11, MAX-11i, MAX 12, MAX 12A, MAX-12F,
MAX-13, MAX-13F, MAX-14, MAX-16, MAX-17, MAX-19,
MAX-22CC & MAX-250ESF

Classification and GMDN: IIa Sensor, Oxygen - 13538

Classification criteria: Clause 1.2 Rule 2 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: 15 April 2001

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

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

Name: Tammy Lavery, RAC
Position: Director of Regulatory & Quality/Maxtec Management Representative
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SECTION 13 REV N
RF192 REV B