



SENSING . ANALYSIS . DELIVERY .

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-3, MAX-7, MAX-9, MAX-10, MAX-11, MAX-11i, MAX-12,
MAX-12A, MAX-12C, MAX-13, MAX-13C, MAX-13CS, MAX-14, MAX-16,
MAX-16HT, MAX-17, MAX-18, MAX-19, MAX-23, MAX-23C, MAX-24,
MAX-40, MAX-43, MAX-47, MAX-48 & MAX-250ESF

Classification & 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 -0123
RIDLERSTRASSE 65, D-80339 MUNICH, Germany

EC Certificate No.: G1 14 06 45041 014

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: 9-2-2014

Name: Tammy Lavery
Position: Director of Regulatory & Quality/Maxtec Management Representative



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Applied Standards

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

EN ISO 13485:2012

DIN 60601-1

DIN EN 12598