maxtec

SENSING. ANALYSIS. DELIVERY.

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 Sensors
Model(s):	Max-2, Max-13-250, Max-550 (E and CUI), Max-125M and Max-250 (+, A, E, K, MK, MKT, MS, MST, TA, TE, TEL, TL, TM, SLE, XPCB)
Classification & GMDN:	IIa - GMDN 13538 – Sensor, Oxygen
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 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:	15 June 2000

This declaration is considered valid from May 11, 2020 to December 18, 2021.

Signature: Tammy Lavery Date: 5/11/2020

Name: Tammy Lavery

Position: Director of Regulatory Affairs

Applied Standards

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

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