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 Hommerterweg 286 6436 AM Amstenrade The Netherlands
Product:	MaxO2ME Oxygen Monitor
Model(s):	MaxO2ME
Classification & GMDN:	IIb Analyzer, Gas, Oxygen - 35219
Classification criteria:	Clause 3.1 Rule 9 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 -123 RIDLERSTRASSE 65, D-80339 MUNICH, Germany
EC Certificate No.:	G1 15 03 45041 017
Date CE mark was affixed:	5/14/16

This declaration is considered valid from 5/14/16 to 12/18/16

Signature: _____ Date: 6/16/16

Name: Bruce Brierley
Position: CEO

Applied Standards

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

ISO 80601-2-55:2011
EN ISO 14971:2012
IEC 60601-1:2005
IEC 60601-1-2:2014
CAN/CSA C22.2 NO. 60601-1:14
EN 62366:2008
EN 1041:2008
ISO 15223-1:2012
EN ISO 10993-1:2009
ISTA 2A
EN 50581:2012