maxtec

premier O2 solutions

DECLARATION OF CONFORMITY

Manufacturer's Name and Address	**Maxtec** **6526 South Cottonwood Street** **Salt Lake City, Utah 84107** **USA**
EC REP **European Representative:**	**QNET BV** **Hommerterweg 286** **6436 AM Amstenrade** **The Netherlands**
Product:	**FloCap**
Model(s):	**R500P21**
Classification & GMDN:	**Class IIa GMDN 17614 Oesophageal intubation detector, exhaled carbon dioxide, adult**
Classification Criteria:	**Clause 1.2 Rule 2 of Annex IX of MDD**

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the following EC Council Directives and applicable standards (page 2). 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:	**November 19, 2013**

This declaration is considered valid from November 19, 2013 to December 18, 2016

Signature: Tammy Lavery **Date:** 8-26-2014

Name: **Tammy Lavery**
Position: **Director of Regulatory & Quality**
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TF0022 Section 13 Rev A

RF192 REV D

Applied Standards

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

EN ISO 14971-2007
EN 62366:2008
ISO 15223-1:2012
EN 1041:2008
EN ISO 10993-1:2009