ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 15 03 45041 017

Manufacturer:

Maxtec
2305 South 1070 West
Salt Lake City UT 84119
USA

EC-Representative:

QNET BV
Hommerterweg 286
6436 AM Amstenrade
THE NETHERLANDS

Product Category(ies):

Electrochemical Oxygen Sensors, Analyzers, Monitors, Air/Oxygen Blenders, Flowmeters and CO2 Indicators

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72103033

Valid from: 2015-04-13
Valid until: 2016-12-18

Date, 2015-04-14

H.-H.

Hans-Heiner Junker

628136

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstrasse 65 · 80339 München · Germany

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