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Date: 2021.09.24 15:00:46 EEST
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Location: Moldova

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 16 10 96122 004

Manufacturer:

Analytical Industries Inc.
2855 Metropolitan Place
Pomona CA 91767
USA

EC-Representative:

Distribuciones y Respresentaciones Biomedicas Direx, S.L
Avda. San Pablo, 28. Nave 24
2882 Coslada Madrid
SPAIN

Product Category(ies):

Oxygen Sensors, Analyzers and Monitors

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.: 72117342

Valid from: 2017-02-03
Valid until: 2022-02-02

Date, 2017-02-03

Stefan Preiß

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

TÜV®

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)
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No. G1 16 10 96122 004

Facility(ies):

Analytical Industries Inc.
2855 Metropolitan Place, Pomona CA 91767, USA

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

TÜV®

CERTIFICATE

EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the company

IT Dr. Gambert GmbH

Scope of certification:

Design and development, manufacture and distribution of electro-chemical gas sensors for medical equipment

Certified location:

Hinter dem Chor 21, 23966 Wismar, Germany

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 50403-Z6-00.

This certificate is valid from 2018-09-17 to 2021-09-16

Registration No.: 50403-14-00

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15, D-70565

DEKRA Certification

DAkkS Deutsche Akkreditierungsstelle D-ZM-16029-08-00

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-08-31