ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ 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 02 14553 037

Manufacturer:

Biegler GmbH
Allhangstrasse 18 a
3001 Mauerbach
AUSTRIA

Facility(ies):

Biegler GmbH
Allhangstrasse 18 a, 3001 Mauerbach, AUSTRIA

Product Category(ies):

Ventilators and respiratory training apparatus, blood and infusion warmers, cooling systems for medical solutions, electrical stimulation therapy devices, pressure infusion devices, extension sets for blood- and infusionwarmer, heating bag systems and biopsy needles, active dental pump system

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.: 713057373

Valid from: 2015-03-20
Valid until: 2020-03-19

Date, 2015-03-12

Hans-Heiner Junker

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