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 14 08 54221 010

Manufacturer:

Compumedics Germany GmbH
Josef-Schüttler-Str. 2
78224 Singen
GERMANY

Facility(ies):

Compumedics Germany GmbH
Josef-Schüttler-Str. 2, 78224 Singen, GERMANY

Product Category(ies):

Medical systems for ultrasound diagnosis, monitoring, therapeutic and patient monitoring devices and their accessories

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.: 713048108

Valid from: 2014-10-26
Valid until: 2019-10-25

Date, 2014-10-27

Hans-Heiner Junker

609144

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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