Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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 054221 0015 Rev. 00

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 and patient monitoring devices and ultrasound probes

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.: 713162009

Valid from: 2019-10-26
Valid until: 2024-05-26

Date, 2019-10-21

Stefan Preiß
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany