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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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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.

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

Date, 2019-10-21

Stefan Preiß
Head of Certification/Notified Body