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 066557 0002 Rev. 01

Manufacturer: **Comcotec Messtechnik GmbH**
Gutenbergstrasse 3
85716 Unterschleißheim
GERMANY

Facility(ies): Comcotec Messtechnik GmbH
Gutenbergstrasse 3, 85716 Unterschleißheim, GERMANY

Product Category(ies): **Software for control and documentation of disinfection and sterilization processes, for the release of sterilized medical devices, as well as for the calculation of stability data of sterilized medical devices**

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.: 713157565

Valid from: 2019-07-29
Valid until: 2024-05-26

Date, 2019-07-29

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD
A4 / 07.17