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

TÜV SÜD 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 023971 0037 Rev. 00

Manufacturer:

em-tec GmbH
Lerchenberg 20
86923 Finning
GERMANY

Facility(ies):

em-tec GmbH
Lerchenberg 16, 86923 Finning, GERMANY

em-tec GmbH
Lerchenberg 20, 86923 Finning, GERMANY

Product Category(ies): **Level Sensors for Blood and Fluid Reservoirs and Ultrasonic Probes for the Volumetric Measurement of Liquids flowing through Vessels, Tubes or Grafts: sterile or non-sterile**

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.: 713154151

Valid from: 2019-04-10
Valid until: 2024-04-09

Date, 2019-04-10

Stefan Preiß

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

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

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