



Product Service

Certificate

No. Q5 023971 0035 Rev. 01

Holder of Certificate: **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

Certification Mark:



Scope of Certificate: Design and Development, Production, Distribution and Servicing of Modules for Heart-Lung Machines/ Assist Systems and Dialysis Machines, Level Sensors for Reservoirs, Ultrasonic Flow-meter and Probes for Volumetric Measurement of Liquids flowing through Vessels, Tubes or Grafts including sterile products. Contract Development for Medical Devices

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713169634

Valid from: 2020-02-01

Valid until: 2023-01-31

Date, 2020-01-10

Christoph Dicks
Head of Certification/Notified Body

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE