



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 023971 0035 Rev. 05

Holder of Certificate: **em-tec GmbH**

Lerchenberg 20
86923 Finning
GERMANY

Facility(ies):

em-tec GmbH

Lerchenberg 20, 86923 Finning, GERMANY

See Scope of Certificate

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 Flowmeter and Probes for Volumetric Measurement of Liquids flowing through Vessels, Tubes or Grafts.
Contract Development for Medical Devices

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

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). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 023971 0035 Rev. 05](http://www.tuvsud.com/ps-cert?q=cert:Q5_023971_0035_Rev.05)

Report No.: 713379145

Valid from: 2026-02-01

Valid until: 2029-01-31

Date, 2025-11-27

Christoph Dicks

Head of Certification/Notified Body