



Product Service

# Certificate

No. Q5 023971 0035 Rev. 02

**Holder of Certificate:** **em-tec GmbH**  
 Lerchenberg 20  
 86923 Finning  
 GERMANY

**Facility(ies):** em-tec GmbH  
 Lerchenberg 20, 86923 Finning, GERMANY

em-tec GmbH  
 Am Graben 6-8, 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.:** 713184528  
**Valid from:** 2020-05-11  
**Valid until:** 2023-01-31

**Date,** 2020-05-11

Christoph Dicks  
 Head of Certification/Notified Body