



Certificate

No. Q5 023971 0035 Rev. 03

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

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 and certification regulation of 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. 03

Report No.: 713256866

Valid from: 2023-02-01

Valid until: 2026-01-31

Date, 2023-01-26



Christoph Dicks
Head of Certification/Notified Body

Certificate

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

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

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.
Contract Development for Medical Devices

em-tec GmbH
Am Graben 6-8, 86923 Finning, GERMANY

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and Servicing of Modules for Heart-Lung Machines/
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Parameters: n/a