



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 094663 0003 Rev. 04

Holder of Certificate: **ewimed GmbH**
Dorfstraße 24
72379 Hechingen-Boll
GERMANY

Certification Mark:



Scope of Certificate: **Design and development, production and distribution of sterile and unsterile, active and nonactive, implantable and non-implantable medical devices and procedure packs in the cardiological and oncological area, mainly drainage systems as well as the provision of related application trainings**

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 094663 0003 Rev. 04](http://www.tuvsud.com/ps-cert?q=cert:Q5_094663_0003_Rev_04)

Report No.: 713373632

Valid from: 2025-10-08
Valid until: 2028-10-07

Date, 2025-10-02

Christoph Dicks
Head of Certification/Notified Body



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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

Facility(ies): **ewimed GmbH**
Dorfstraße 24, 72379 Hechingen-Boll, GERMANY

Top-Management, Quality Management including PMS, Design
und Development, Regulatory Affairs for sterile and unsterile,
active and nonactive, implantable and non-implantable medical
devices and procedure packs in the cardiological and oncological
area, mainly drainage systems as well as the provision of related
application trainings

ewimed GmbH
Josef-Baur-Str. 1, 72379 Hechingen-Boll, GERMANY

Top-Management, Quality Management including PMS,
Regulatory Affairs, Purchasing Controls including Production- and
Process-Controls and Marketing for sterile and unsterile, active
and nonactive, implantable and non-implantable medical devices
and procedure packs in the cardiological and oncological area,
mainly drainage systems as well as the provision of related
application trainings

ewimed GmbH
Weißkreuzstraße 12, 72379 Hechingen-Boll, GERMANY

Warehousing for sterile and unsterile, active and nonactive,
implantable and non-implantable medical devices and procedure
packs in the cardiological and oncological area, mainly drainage
systems

ewimed GmbH
Im Nasswasen 3, 72379 Hechingen, GERMANY

Warehousing and distribution of sterile and unsterile, active and
nonactive, implantable and non-implantable medical devices and
procedure packs in the cardiological and oncological area, mainly
drainage systems