



Certificate

No. Q5 010066 0435 Rev. 02

Holder of Certificate: **AESCU LAP AG**
Am Aesculap-Platz
78532 Tuttlingen
GERMANY

Certification Mark:



Scope of Certificate: see attachment page 4 and 5

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 010066 0435 Rev. 02

Report No.: 713387461

Valid from: 2026-06-01
Valid until: 2029-05-31

Date, 2026-05-26

Christoph Dicks
Head of Certification/Notified Body



Certificate

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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): **AESCULAP AG**
Am Aesculap-Platz, 78532 Tuttlingen, GERMANY

Design and Development, Production and Distribution of

- non-sterile and reusable, active devices for insufflation
- non-sterile and reusable, active motorized surgery systems
- non-sterile and reusable, active visualisation systems for endoscopic surgery
- non-sterile and reusable, non-active dental instruments
- non-sterile and reusable, non-active devices for high frequency surgery
- non-sterile and reusable, non-active sterilization container systems for storage and transport
- non-sterile, active devices for high frequency surgery
- sterile, non-active implants and non-sterile, reusable, non-active instruments for hip arthroplasty
- sterile, non-active implants and non-sterile, reusable, non-active instruments for knee arthroplasty
- sterile, non-active soft tissue implants with and without materials of animal origin
- sterile, non-sterile and reusable, active devices for suction and irrigation
- sterile, non-sterile and reusable, active instruments for surgical procedures
- sterile, non-sterile and reusable, active seal & cut instruments for open and minimal invasive surgical procedures
- sterile, non-sterile and reusable, non-active devices for insufflation
- sterile, non-sterile and reusable, non-active devices for ligation
- sterile, non-sterile and reusable, non-active devices for robotic surgery
- sterile, non-sterile and reusable, non-active devices for suction and irrigation
- sterile, non-sterile and reusable, non-active endoscopic devices for neurosurgery
- sterile, non-sterile and reusable, non-active instruments for surgical procedures
- sterile, non-sterile and reusable, non-active instruments for neurosurgery
- sterile, non-sterile and reusable, non-active minimally invasive instruments for endoscopic surgery
- sterile, non-sterile and reusable, non-active instruments for use with active motorized surgery systems
- sterile, non-sterile, non-active implants and sterile, non-sterile, reusable, non-active instruments for spinal surgery
- sterile, non-sterile, non-active implants and sterile, non-sterile, reusable, non-active instruments for trauma surgery
- sterile, non-sterile, reusable, non-active implants and non-sterile, reusable, non-active instruments for cranial surgery



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Design and Development, Production, Installation and Distribution of

- non-sterile and reusable, active devices for robotic surgery and related software
- sterile, non-sterile and reusable devices for navigation systems and related software

Design and Development and Distribution of

- sterile, non-active instruments for vascular surgery
- sterile, non-active implants for vascular surgery with materials of animal origin

The provision of

- servicing of instruments for surgical procedures, motorized surgery systems, sterilization container systems, navigation systems and devices for robotic surgery
- surface treatment of instruments for surgical procedures
- warehousing and distribution services of non-active implants and instruments for surgical procedures including shunt systems and catheters

AESCULAP AG

Carl-Braun-Str. 1, 34212 Melsungen, GERMANY

The production of

- sterile, non-active soft tissue implants with and without materials of animal origin

The provision of

- manufacturing service for local haemostatics
- manufacturing service for sterile non-active soft tissue implants with materials of animal origin



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Design and Development, Production and Distribution of

- non-sterile and reusable, active devices for insufflation
- non-sterile and reusable, active motorized surgery systems
- non-sterile and reusable, active visualisation systems for endoscopic surgery
- non-sterile and reusable, non-active dental instruments
- non-sterile and reusable, non-active devices for high frequency surgery
- non-sterile and reusable, non-active sterilization container systems for storage and transport
- non-sterile, active devices for high frequency surgery
- sterile, non-active implants and non-sterile, reusable, non-active instruments for hip arthroplasty
- sterile, non-active implants and non-sterile, reusable, non-active instruments for knee arthroplasty
- sterile, non-active soft tissue implants with and without materials of animal origin
- sterile, non-sterile and reusable, active devices for suction and irrigation
- sterile, non-sterile and reusable, active instruments for surgical procedures
- sterile, non-sterile and reusable, active seal & cut instruments for open and minimal invasive surgical procedures
- sterile, non-sterile and reusable, non-active devices for insufflation
- sterile, non-sterile and reusable, non-active devices for ligation
- sterile, non-sterile and reusable, non-active devices for robotic surgery
- sterile, non-sterile and reusable, non-active devices for suction and irrigation
- sterile, non-sterile and reusable, non-active endoscopic devices for neurosurgery
- sterile, non-sterile and reusable, non-active instruments for surgical procedures
- sterile, non-sterile and reusable, non-active instruments for neurosurgery
- sterile, non-sterile and reusable, non-active minimally invasive instruments for endoscopic surgery
- sterile, non-sterile and reusable, non-active instruments for use with active motorized surgery systems
- sterile, non-sterile, non-active implants and sterile, non-sterile, reusable, non-active instruments for spinal surgery
- sterile, non-sterile, non-active implants and sterile, non-sterile, reusable, non-active instruments for trauma-surgery
- sterile, non-sterile, reusable, non-active implants and non-sterile, reusable, non-active instruments for cranial surgery



Certificate

No. Q5 010066 0435 Rev. 02

Design and Development, Production, Installation and Distribution of

- non-sterile and reusable, active devices for robotic surgery and related software
- sterile, non-sterile and reusable devices for navigation systems and related software

Design and Development and Distribution of

- sterile, non-active instruments for vascular surgery
- sterile, non-active implants for vascular surgery with materials of animal origin

The provision of

- manufacturing service for local haemostatics
- manufacturing service for sterile non-active soft tissue implants with materials of animal origin
- servicing of instruments for surgical procedures, motorized surgery systems, sterilization container systems, navigation systems and devices for robotic surgery
- surface treatment of instruments for surgical procedures
- warehousing and distribution services of non-active implants and instruments for surgical procedures including shunt systems and catheters