



Certificate

No. Q5 010066 0435 Rev. 01

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

Certification Mark:



Scope of Certificate: Design and development, production, distribution and service of sterile and reusable non-active, non-implantable surgical and dental instruments

Design and development, production, distribution and service of active non-implantable surgical devices

Design and development, production and distribution of sterile and non-sterile, non-active cardiovascular, vascular, neurovascular and ligation implants

Design and development, production and distribution of sterile non-active osteo-, orthopaedic and cranial implants

Design and development, production and distribution of sterile non-active soft tissue implants with and without animal origin material

Design and development, production and distribution of sterile and reusable non-active devices for injection and infusion

Design and development, production and distribution of sterile surgical instruments, non-active medical devices with measuring function, sterile containers and related accessories

Design and development, production, installation and distribution of active non-implantable imaging devices

Design and development, production, installation and distribution of Software

The provision of manufacturing service of sterile Non-active soft tissue implants with animal origin material

The provision of manufacturing service of tissue adhesives and local haemostatics

Certificate

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The provision of warehousing and distribution for medical device

The provision of service for medical devices, incl. implants

The provision of surface treatment 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 010066 0435 Rev. 01

Report No.: 713280758

Valid from: 2023-06-01

Valid until: 2026-05-31

Date, 2023-04-25



Christoph Dicks
Head of Certification/Notified Body

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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):

AESCULAP AG

Am Aesculap-Platz, 78532 Tuttlingen, GERMANY

Design and development, production, distribution and service of
sterile and reusable non-active, non-implantable surgical and
dental instruments

Design and development, production, distribution and service of
active non-implantable surgical devices

Design and development, production and distribution of sterile and
non-sterile, non-active cardiovascular, vascular, neurovascular and
ligation implants

Design and development, production and distribution of sterile
non-active osteo-, orthopaedic and cranial implants

Design and development, production and distribution of sterile
non-active soft tissue implants with and without animal origin
material

Design and development, production and distribution of sterile and
reusable non-active devices for injection and infusion

Design and development, production and distribution of sterile
surgical instruments, non-active medical devices with measuring
function, sterile containers and related accessories

Design and development, production, installation and distribution
of active non-implantable imaging devices

Design and development, production, installation and distribution
of Software

The provision of warehousing and distribution for medical device

The provision of service for medical devices, incl. implants

The provision of surface treatment for medical devices

Certificate

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Facility(ies):

AESCLAP AG

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

Production of sterile non-active soft tissue implants with and without animal origin material

The provision of manufacturing service of tissue adhesives and local haemostatics

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