ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

# Certificate

## No. Q5 010066 0435 Rev. 01

**Holder of Certificate:**

**AESCULAP AG**
Am Aesculap-Platz
78532 Tuttlingen
GERMANY

Trưởng phòng đăng ký
CÔNG TY TRÁCH NHIỆM HỮU HẠN B.BRAUN VIỆT NAM
Trịnh Thị Linh

Digitally signed by CÔNG TY TNHH B.BRAUN VIỆT NAM

**Certification Mark:**

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

**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**


TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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# Certificate

## No. Q5 010066 0435 Rev. 01

**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


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Product Service

# Certificate

## No. Q5 010066 0435 Rev. 01

## Facility(ies):

**AESCULAP 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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