B|BRAUN

Aesculap AG
Regulatory Affairs

Postfach 40
78501 Tuttlingen
Germany

Contact: Nicole Consiglio

Fon: +49 7461 95-31479
Fax: +49 7461 95-2969
Email: nicole.consiglio@aesculap.de
Internet: http://www.bbraun.com

Date: June 02, 2017

To the responsible authority of
Vietnam

Das Zertifikat

Nr. **Q5 17 03 10066 408**

ausgestellt von TÜV Süd Product Service in München (DE) dient der Vorlage bei der zuständigen Behörde von **Vietnam**.

The certificate

No. **Q5 17 03 10066 408**

is issued by TÜV Süd Product Service in München, Germany for presentation to the responsible authority of **Vietnam**.

AESCULAP AG

i. V.

Dr. Stefan Willemsen
Regulatory Affairs

i. A.

Nicole Consiglio
Regulatory Affairs

INDUSTRIE- UND HANDELSKAMMER SCHWARZWALD-BAAR-HEUBERG

Industrie- und Handelskammer
Schwarzwald - Baar - Heuberg
Wir bescheinigen die Vorlage der Erklärung. Hinsichtlich des Inhalts ist nichts Gegenteiliges bekannt.
78050 Villingen-Schwenningen,

den 07. JUNI 2017

Winker-Jerkovic

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTI

CERTIFICATE

No. Q5 17 03 10066 408

Product Service

Holder of Certificate:

AESCULAP AG
Am Aesculap-Platz
78532 Tuttlingen
GERMANY

Facility(ies):

AESCULAP AG
Am Aesculap-Platz, 78532 Tuttlingen,
GERMANY

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

Certification Mark:

TÜV SÜD DIN EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate:

Design and development, production, technical service and distribution of implants, instruments, instrument management systems, containers, devices, tissue adhesives and procedure kits (for detailed information see attachment)

Applied Standard(s):

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

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). See also notes overleaf.

Report No.: 713098053

Valid from: 2017-06-01
Valid until: 2020-05-31

Date, 2017-05-30

Stefan Preiß

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

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

DAkkS CRT2 / 10.13

TÜV SÜD
Product Service

Attachment for certificate no Q5 17 03 10066 408
dated 2017-06-01

- Surgical, diagnostic and dental instruments
- Joint implants (hip, knee)
- Spinal implants
- Implants for osteosynthesis
- Neurosurgical vascular implants
- Products for ligature
- Motor systems
- Sterilization containers and accessories
- High frequency surgery devices
- Endoscopie systems
- Navigation systems
- Surgical suction pumps
- Special suture-sets
- Implants for replacement of connective tissue
- Tissue adhesives
- Vascular prostheses and accessories
- Local haemostatics
- Other surgical accessories

Munich, CRT2 2017-05-30

Stefan Preiß

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

TÜV®

TỔNG LÃNH SỰ QUÁN NƯỚC CHXHCN VIỆT NAM
tại Frankfurt am Main, CHLB Đức

1. Quốc gia: **Việt Nam**
Country:

Giấy tờ, tài liệu này
This public document

2. do Ông (Bà): **Winker - Jerkovic**
has been signed by:

3. với chức danh: **Cán bộ phụ trách**
acting in the capacity of:

4. và con dấu của: **Phòng Công nghiệp & Thương mại**
bears the seal/stamp of: **vùng Schwarzwald - Baar - Heuberg**

được chứng nhận / hợp pháp hóa lãnh sự
Certified

5. tại: **Frankfurt** 6. ngày: **09/06/2017**
at: *on:*

7. Cơ quan cấp: **Tổng lãnh sự quán Việt Nam tại Frankfurt/Main**
by:

8. Số: **706/2017/CN-HPHLS**
No:

TL. Tổng Lãnh sự / For Consul General
Phó lãnh sự / Vice-Consul

Nguyễn Đức Linh