



Product Service

CERTIFICATE

No. Q5 17 10 38951 011

Holder of Certificate: **AESCULAP CHIFA Sp. z o.o.**

ul. Tysiaclecia 14
64-300 Nowy Tomysl
POLAND

Facility(ies):

AESCULAP CHIFA Sp. z o.o.
ul. Tysiaclecia 14, 64-300 Nowy Tomysl,
POLAND

Aesculap Chifa Sp. z o.o.
ul. Budowlanych 1a, 21-300 Radzyn Podlaski,
POLAND



Certification Mark:



Scope of Certificate:

**Design and development, production, distribution and technical service of surgical instruments.
Production and completion of vascular products and related surgical vascular accessories.
Distribution and technical service of medical devices.
Distribution of medical products.**

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.: 713115342

Valid from: 2017-11-01

Valid until: 2020-10-31



Date, 2017-10-23

Stefan Preiß

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

Aesculap AG
Regulatory Affairs

Postfach 40
78501 Tuttlingen
Germany

Contact: Nicole Consiglio

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Fax: +49 7461 95-2969

Email: nicole.consiglio@aesculap.de

Internet: <http://www.bbraun.com>

Date: March 21, 2017

To the responsible authority of
Vietnam



Das Zertifikat

Nr. ^{Q2N} 01N 16 07 14432 027

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

The certificate

No. ^{Q2N} 01N 16 07 14432 027

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

AESCULAP AG

i. V.


Mandy Blocher
Regulatory Affairs

i. A.


Nicole Consiglio
Regulatory Affairs



**Industrie- und Handelskammer
Schwarzwald - Baar - Heuberg**

Wir bescheinigen die Vorlage der
Erklärung. Hinsichtlich des Inhalte
ist nichts Gegenteiliges bekannt.
78050 Villingen-Schwenningen,

den **24. MRZ 2017**

Winker-Jerkovtc

Chairman of Supervisory Board:
Prof. Dr. h.c. Ludwig Georg Braun

Executive Board:
Prof. Dr. Hanns-Peter Knaebel
(Chairman)
Dr. Jens von Lackum
Dr. Joachim Schulz

Corporate Office: Tuttlingen
Register Court: Stuttgart HRB 726261
VAT reg. no. DE812160059

WEEE-Reg.-No. DE 65109852

Bank Account:
Deutsche Bank AG Tuttlingen
BLZ 653 700 75 Konto 21 22 000 00
IBAN DE44 6537 0075 0212 2000 00
SWIFT / BIC DEUTDE33

Baden-Württembergische Bank
BLZ 600 501 01 Konto 487 1905
IBAN DE31 6005 0101 0004 8719 05
SWIFT / BIC SOLADEST

Address:
Aesculap AG
Am Aesculap-Platz
78532 Tuttlingen
Germany



Product Service

CERTIFICATE

No. Q2N 16 07 14432 027

Holder of Certificate: **B. Braun Medical Industries Sdn. Bhd.**
 Bayan Lepas Free Industrial Zone
 11900 Penang
 MALAYSIA

Facility(ies): B. Braun Medical Industries Sdn. Bhd.
 Bayan Lepas Free Industrial Zone, 11900
 Penang, MALAYSIA



Certification Mark:



tuv-sud.com/ps-cert

Scope of Certificate: **Production and Distribution of Surgical Instruments, Disposable Surgical Blades**

Applied Standard(s): EN ISO 13485:2012 + AC:2012
 Medical devices - Quality management systems -
 Requirements for regulatory purposes
 (ISO 13485:2003 + Cor. 1:2009)
 DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: MYQMH0516056-721415447

Valid from: 2016-09-01
Valid until: 2019-08-31



Date, 2016-08-19


 Stefan Preiß

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CERTIFICATE ◆ CERTIFICADO ◆ CERTIFIKAT ◆ 認証證書 ◆ ZERTIFIKAT ◆ CERTIFICATE



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**CHỨNG NHẬN/ HỢP PHÁP HÓA LÃNH SỰ
KONSULARISCHE BEGLAUBIGUNG/LEGALISIERUNG**

1. Quốc gia/Staat: **Việt Nam/Vietnam**

Giấy tờ, tài liệu này/Dieses Dokument

2. Với chữ ký của/U. von Herr (Frau): **Winker-Jerkovic**

3. Với chức danh/Funktion: **Nhân viên hành chính**

4. Và con dấu của/Dienstsigel von: **Phòng Thương mại và Công nghiệp Schwarzwald-Baar-Heuberg**

**được chứng nhận/hợp pháp hóa lãnh sự/
wird hiermit konsularisch beglaubigt/legalisiert**

5. Tại/in: **Berlin**

6. Ngày/Datum: **12/04/2017**

7. Cơ quan cấp/Ausgestellt von: **Đại sứ quán nước CHXHCN Việt Nam tại CHLB Đức Botschaft der SR Vietnam in der BR Deutschland**

8. Số/Nr.: **04b-LS-HPH/2017**

Tl. Đại sứ/i.A. des Botschafters
Tham tán/Botschaftsrätin

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Lê Thị Thu

