

Aesculap AG
Regulatory Affairs

Postfach 40
78501 Tuttlingen
Germany

To the responsible authority of
Vietnam

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Date: January 19, 2018

Das Zertifikat

Nr. **Q5 17 10 38951 011**

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


The certificate

No. **Q5 17 10 38951 011**

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**

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

den **19. JAN. 2018**

Winker-Jerkovt

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

Executive Board:
Dr. Joachim Schulz
(Chairman)
Dr. Jens von Lackum

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. Q5 17 10 38951 011

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

ul. Tysiaclecia 14
64-300 Nowy Tomysl
POLAND

Facility(ies):

AESFULAP 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



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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** ký
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 và Thương mại**
bears the seal/stamp of: Schwarzwald-Baar-Heuberg
được chứng nhận / hợp pháp hóa lãnh sự
Certified

5. tại: **Frankfurt** 6. ngày: **09/05/2018**
at: the:

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

8. Số: **664/2018/CN-HPHLS**
No:

TL. Tổng Lãnh sự / For Consul General
Lãnh sự / Consul



Nguyễn Nam Hải