

**Aesculap AG
Regulatory Affairs**

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78501 Tuttlingen
Germany

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Date: October 09, 2019

To the responsible authority of
Vietnam



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

den **09. OKT. 2019**

Winker-Jerkovic

Die CE Declaration

vom 07. Oktober 2019

ausgestellt von der Aesculap AG in Tuttlingen (DE)
dient der Vorlage bei der zuständigen Behörde von
Vietnam.

The CE Declaration

dated October 07, 2019

is issued by Aesculap AG in Tuttlingen, Germany
for presentation to the responsible authority of
Vietnam.

AESCULAP AG

i. A.

Nicole Consiglio
Regulatory Affairs

i. A.

Nadine Krämer
Regulatory Affairs

Chairman of Supervisory Board:
Prof. Dr. Heinz-Walter Große

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

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 SOLADE33

Address:
Aesculap AG
Am Aesculap-Platz
78532 Tuttlingen
Germany



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 Herrn (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**

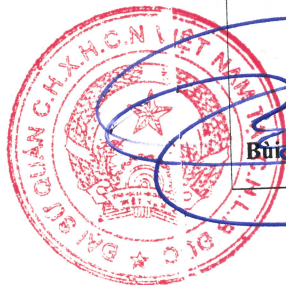
5. Tại/in: **Berlin**

6. Ngày/Datum: **17/10/2019**

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.: **10c-LS-HPH/2019**

TL. Đại sứ/i.A. des Botschafters
Bí thư thứ ba/III. Sekretär



Bùi Đức Minh

Declaration

The certification body of TÜV Süd Management Service GmbH and the TÜV Süd Product Service GmbH confirm that we,

AESFULAP AG
AM AESFULAP-PLATZ
78532 TUTTLINGEN / GERMANY

have established and are maintaining a quality management system according to

ISO 9001:2015

(Certificate Registration No.: 12 100 21724 TMS)

EN ISO 13485:2016

(Certificate No.: Q5 17 03 10066 408)

for the following area

**Development, Production and Distribution of Implants, Instruments, Containers,
Devices, Suture Material, Tissue Adhesives and Procedure Kits.**

Furthermore we have implemented the conformity assessment procedure as per annex II, clause 3 of the Medical Device Directive 93/42/EEC of June 14th, 1993 for medical products (TÜV EC-Certificate No.: G1 14 05 10066 366 or MEDCERT EC-Certificate No.: 7400GB410170801).

By labeling the products

as per attached list

with the CE mark

we, **AESFULAP AG** confirm,
that we follow the essential requirements
according to MDD 93/42/EEC Annex I.

TUTTLINGEN, 2019-10-07

AESFULAP AG

i. V.


Mandy Blocher
Regulatory Affairs

i. A.


Nicole Consiglio
Regulatory Affairs

Attachment to Declaration

| Aesculap Product Groups |
|--|
| 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 and accessories |
| Endoscopic 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 |



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