For the presentation to Vietnamese authorities

Certificate international EN ISO 13485 : 2012 + AC 2012, registration no. 306732 MP2012
Certificate EN ISO 13485 : 2012 + AC : 2012, registration no. 306732 MP 2012,
and Certificate ISO 9001 : 2008, registration no. 306732 QM08
EC-Certificate, registration no. 306732 MR2 with annex

issued on 2015-08-24 by DQS Medizinprodukte GmbH in Frankfurt am Main

valid until 2018-08-23

ZEPF MEDICAL INSTRUMENTS GMBH

Jochen Thomas Zepf
Geschäftsführer

ZEPF MEDICAL INSTRUMENTS GmbH
GUNNINGER STRASSE 21
D-78606 SEITINGEN-OBERFLACHT
GERMANY

CERTIFICATE

This is to certify that the company

Zepf Medical Instruments GmbH
Gunningerstraße 21
78606 Seitingen-Oberflacht
Germany

has implemented and maintains a **Quality Management System**.

Scope:
Design, Manufacturing, Marketing and sale of surgical instruments and implants for Osteosynthesis, Sterile Disposable Scalpels and Sterile Scalpel Blades

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001 : 2008

Certificate registration no.	306732 QM08
Certificate unique ID	170629325
Effective date	2015-08-24
Expiry date	2018-08-23
Frankfurt am Main	2015-08-24

Deutsche Akkreditierungsstelle D-ZM-16021-02-00

DQS Medizinprodukte GmbH

Frank Graichen
Managing Director

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

20150519/3/EN3803111

CERTIFICATE

This is to certify that the company

Zepf Medical Instruments GmbH
Gunningerstraße 21
78606 Seitingen-Oberflacht
Germany

has implemented and maintains a **Quality Management System**.

Scope:
Design, Manufacturing, Marketing and sale of surgical instruments and implants for Osteosynthesis, Sterile Disposable Scalpels and Sterile Scalpel Blades

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

EN ISO 13485 : 2012 + AC : 2012

Certificate registration no.	306732 MP2012
Certificate unique ID	170624735
Effective date	2015-08-24
Expiry date	2018-08-23
Frankfurt am Main	2015-08-24

DAkkS Deutsche Akkreditierungsstelle D-ZM-16021-01-01

DQS Medizinprodukte GmbH

Frank Graichen
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

20121211/4/EN380307

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Zepf Medical Instruments GmbH
Gunningerstraße 21
78606 Seitingen-Oberflacht
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Surgical Instruments and Implants for Osteosynthesis according to annex

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	306732 MR2
Certificate unique ID	170624736
Effective date	2015-08-24
Expiry date	2020-08-23
Frankfurt am Main	2015-08-24

DQS Medizinprodukte GmbH

Frank Graichen
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

20120803/2/EN380308

Annex to Certificate
Certificate registration No.: 306732 MR2
Certificate unique ID: 170624736
Effective date: 2015-08-24

Zepf Medical Instruments GmbH

Gunningerstraße 21
78606 Seitingen-Oberflacht
Germany

Device family	Device	Class
Implants for Osteosynthesis from steel and titanium	Bone Nails	IIb
	Bone Plates	IIb
	Bone Screws	IIb
	Bone Wires	IIb
	Osteotomy Staples	IIb
Surgical Instruments	Sterile Disposable Scalpels	IIa
	Sterile Scalpel Blades	IIa
HF / RF - Instruments	Monopolar Forceps	IIb
	Bipolar Forceps	IIb

This annex is only valid in connection with the above-mentioned certificate.

Urkundenrolle II UR 1305 / 2017
Notariat II Tuttlingen* Tel. 07461/98372*Fax 07461/98358

II UZ 1324 / 2017

Notarielle Beglaubigung

Vorstehende, vor mir vollzogene Unterschrift von

Herr Jochen Thomas Zepf,
geboren am 23.10.1961,
geschäftsansässig in 78606 Seitingen-Oberflacht, Gunninger Straße 21,

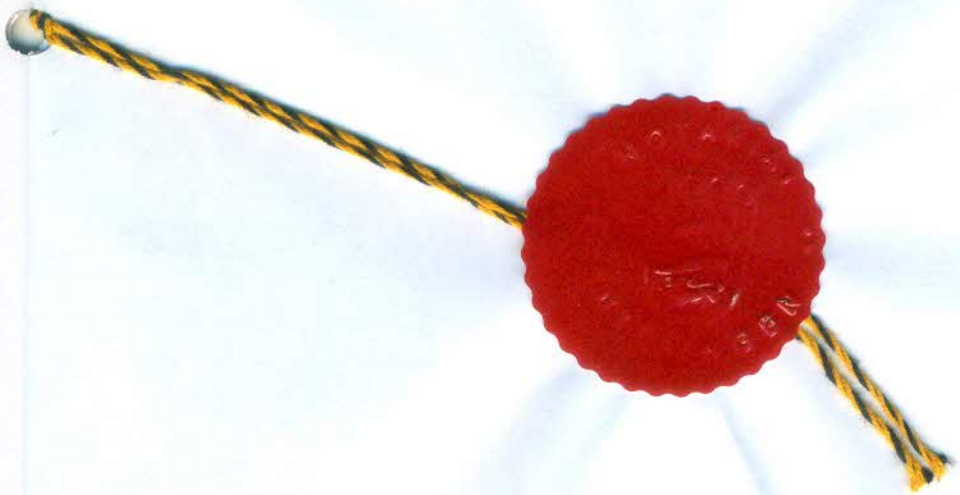
- persönlich bekannt -

beglaubige ich hiermit öffentlich.

Tuttlingen, den 12.07.2017

Notar

(Haller)




LANDGERICHT
ROTTWEIL


LANDGERICHT
ROTTWEIL


LANDGERICHT
ROTTWEIL

Nr. 910 E - 574/17

Die Echtheit vorstehender Unterschrift

des Notars Haller
mit dem Dienstsitz
in Tuttlingen

und die Echtheit des beigedrückten Dienststempels/ Dienstsiegels werden hiermit bestätigt. Zugleich wird bescheinigt, dass der Vorgenannte zur Vornahme der Amtshandlung gesetzlich befugt war.

Rottweil, den 16. August 2017
Präsident des Landgerichts:

LANDGERICHT ROTTWEIL

Dr. Dietmar Foth

Kosten:

Geb. gem. Geb. Verz.
Nr. 1310 zu § 4 Abs. 1
JVKostG: 20,00 €

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

1.Quốcgia/Staat:**Việt Nam/Vietnam**

Giấy tờ, tài liệu này/Dieses Dokument

2.Với chữ ký của/U. von Herrn (Frau): **Dr. Dietmar Foth**
3.Với chức danh/Funktion: **Chánh án**
4. Và con dấu của/Dienstsiegel von: **Tòa án vùng Rottweil**

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

5.Tại/in: **Berlin** 6. Ngày/Datum: **21/08/2017**
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.: **08d-LS-HPH/2017**

11. Đại sứ/i.A. des Botschafters
Bí thư thứ nhất/I. Sekretär

Đinh Anh Tuấn