





TỔNG LÃNH SỰ QUÁN VIỆT NAM TẠI FRANKFURT

**CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION**

1. Quốc gia / Country: Việt Nam
Giấy tờ, tài liệu này
This public document
2. do Ông (Bà) / has been signed by: Dietmar Foth
3. với chức danh / acting in the capacity of: Cán bộ phụ trách
4. và con dấu của / bears the seal/stamp of: Tòa án Rottweil
được chứng nhận / hợp pháp hóa lãnh sự
Certified
5. tại / at: Frankfurt
6. Ngày / the: 10.03.2016
7. Cơ quan cấp: Tổng Lãnh sự quán Việt Nam tại Frankfurt/ Main
By
8. Số / No: 425/2016/CN-HPHLS

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



Nguyễn Thị Thìn

Nr. 910 E - 62/16

Die Echtheit vorstehender Unterschrift

des Notars Werner
mit dem Dienstsitz
in Tuttlingen

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

Rottweil, den 4. Februar 2016
Präsident des Landgerichts




Dr. Dietmar Foth

Kosten:

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



Detlef Werner

Notar

Heinrich-Rieker-Str. 9 - 78532 Tuttlingen

Tel.: 07461/9680-0
Fax: 07461/9680-60
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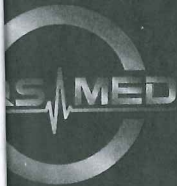
Beglaubigte Abschrift

Die Übereinstimmung nachstehender
Abschrift mit der Urschrift wird beglaubigt.

Tuttlingen, den 24. September 2015




Notar



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

KLS martin
GROUP

Gebrüder Martin GmbH & Co. KG

KLS Martin Platz 1
78532 Tuttlingen
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:

Active and non active medical devices; surgical instruments and units, implants, medical devices for RF- and laser surgery, HF- and laser surgery, ceiling-mounted supply systems and accessories 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.	210299 MR2
Certificate unique ID	170628553
Effective date	2015-08-21
Expiry date	2019-05-26
Frankfurt am Main	2015-08-21

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.

Annex to Certificate
Certificate registration No.: 210299 MR2
Certificate unique ID: 170628553
Effective date: 2015-08-21

Gebrüder Martin GmbH & Co. KG

KLS Martin Platz 1
 78532 Tuttlingen
 Germany

Device family	Devices	Class
RF-surgery units	Medical RF-surgery and HF-surgery units for general and special applications	IIb
HF-surgery units	Argon Beamer	IIb
Accessories for RF-surgery units	Handles for RF-surgery and HF-surgery	IIa / IIb
Accessories for HF-surgery units	Electrodes Forceps and scissors Clamps, forceps, NervScout	
Laser surgery units	surgical laser units for common and particular use	IIb
Accessories for laser surgery units	Laser contact probe Adapter for laser fibres Connection fibres Fibre optics Bipolar suction and irrigation units Micromanipulator	IIb
Implants and Instruments	Distractor Trocar tip for activation arm Condylar implant Washers Meshes (for cranioplasty) Bone plates Bone screws Bone nails Fixation screws Fixation screws (lug) UHP (prosthesis for wrist joint) Tantal wire (orthodontic) Bone clips Bone wire Sternal Talon Finger joint	IIa / IIb
	Aneurysm Clip system permanent and temporary	III
Resorbable Implants	Resorb X meshes Resorb X plates Resorb X screws Resorb X Pins	III



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78532 Tuttlingen
Germany

Device family	Devices	Class
Surgical instruments and units	Sterile scalpels	Ila
	Sterile blades	Ila
	Guide pins	Ilb
	Guide wires	Ilb
	Drill bits OMF surgery	Ila
	BOS driver	Ila
	SonicWeld Rx (basis device, handpieces)	Ila
	SonicWeld Rx (sonotrodes)	Ila
	Drill bits / Saw blades orthopaedic	Ila
	BOS-Battery pack sterile	Is
	Bending Templates	Is
Pendants	Service Head	Ilb
Bone Grafting Material	Martrix	III



Detlef Werner

Notar

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Beglaubigte Abschrift

Die Übereinstimmung nachstehender Abschrift mit der mir vorliegenden Urschrift wird beglaubigt.

Tuttlingen, den 29. Mai 2017




Notarvertreter



CERTIFICATE



This is to certify that the company

KLS martin
GROUP

Gebrüder Martin GmbH & Co. KG

KLS Martin Platz 1
78532 Tuttlingen
Germany

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

Scope:

Development, manufacturing and distribution of medical products, surgical instruments and devices, non-active implants, RF surgery units, operation theatre light systems, ceiling-mounted surgery stands, surgical laser devices and container systems for sterilization and accessories for the above mentioned products.

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.	210299 QM08
Certificate unique ID	170672839
Effective date	2017-05-27
Expiry date	2018-09-14
Frankfurt am Main	2017-05-13



Deutsche
Akkreditierungsstelle
D-ZM-16021-02-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

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



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

1. Quốc gia: **Việt Nam**
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5. tại: **Frankfurt** 6. ngày: **06/07/2017**
at: on:
7. Cơ quan cấp: **Tổng lãnh sự quán Việt Nam tại Frankfurt/Main**
by:
8. Số: **821/2017/CN-HPHLS**
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TL. Tổng Lãnh sự / For Consul General
Lãnh sự / Consul



Nguyễn Thị Thìn



Nr. 910 E - 352/17

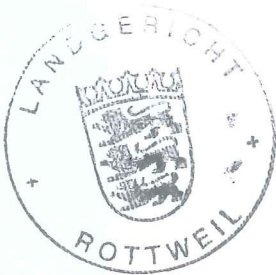
Die Echtheit vorstehender Unterschrift

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als Vertreter des Notars Werner
mit dem Dienstsitz in Tuttlingen

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

Rottweil, den 06.06.2017
Der Präsident des Landgerichts


Dr. Dietmar Foth



Kosten:

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Development, manufacturing and distribution of medical products, surgical instruments and devices, non-active implants, RF surgery units, operation theatre light supply units, ceiling-mounted supply systems, surgical laser devices and container systems for sterilization and accessories for the above mentioned products.

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.	210299 MP2012
Certificate unique ID	170672836
Effective date	2017-05-27
Expiry date	2020-05-26
Frankfurt am Main	2017-05-13



DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body



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Lãnh sự / Consul

Nguyễn Thị Thìn



Nr. 910 E - 353/17

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