



Product Service

CERTIFICATE

No. Q5 17 09 72017 010

Holder of Certificate: MAQUET CRITICAL CARE AB

GETINGE *

 Röntgenvägen 2
 171 54 Solna
 SWEDEN

Facility(ies):

 MAQUET CRITICAL CARE AB
 Röntgenvägen 2, 171 54 Solna, SWEDEN

Certification Mark:

Scope of Certificate: Development, manufacturing and marketing of Anaesthesia, Monitoring and Ventilator Systems

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.: 713109916

Valid from: 2017-12-30
Valid until: 2020-12-29

Date, 2017-11-27

Page 1 of 1

Stefan Preiß



DAKS

 Deutsche
 Akkreditierungsstelle
 D-794 11321-01-00

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

EC CERTIFICATE

for the Quality Assurance System

according the Directive 93/42/EEC,
Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

Maquet Cardiopulmonary GmbH

Kehler Straße 31, 76437 Rastatt, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50008-Z6-00, the decision dated 2017-06-27 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2017-07-10 to 2020-07-09

Registration No.: 50008-16-09



Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2017-06-27
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerksstraße 15 * D-70565 Stuttgart * www.dekra-certification.de



Annex to the EC Certificate No. 50008-16-09

Revision status: 4

Valid from 2018-04-17 to 2020-07-09

Devices/device categories included in the certificate:

Medical Devices for the heart surgery, the intensive care and the cardiology

Class II a:

* Oxygenators:

- QUADROX-i **
 - Adult/Small Adult, microporous membrane
 - Option: with integrated arterial filter
- QUADROX-ID **
 - Adult, diffusion membrane
 - Option: with integrated arterial filter
- QUADROX-j **
 - Neonatal, microporous membrane
 - Option: with integrated arterial filter
- QUADROX-i **
 - Pediatric, microporous membrane
 - Option: with integrated arterial filter
- QUADROX-ID *
 - Pediatric, diffusion membrane

Class II a:

- Venous Hardshell Cardiotomy Reservoir
 - Adult **
 - Pediatric **
 - Neonatal **
- Venous Softbag Reservoir **
- Heat Exchanger PLEGIOX **
- Arterial Filter QUART **
- Tubing Sets and Components **
- Transfer Bags
- Suction Devices
- Venous Bubble Trap **
- Arterial Cannulae *
- Venous Catheters **
- Vent Catheters
- AVALON ELITE Bi-Caval Dual Lumen Catheters
- HLS Cannulae **
- BMU Sensor
- BMU Cell
- Percutaneous Insertion Kits
- Guidewires
- Dilators

Annex to the EC Certificate No. 50008-16-09

Revision status: 4

Valid from 2018-04-17 to 2020-07-09

Devices/device categories included in the certificate:

Medical Devices for the heart surgery, the intensive care and the cardiology

Class II b:

- Hemoconcentrators
- Centrifugal Pump ROTAFLOW * *
- ROTAFLOW Console
- ROTAFLOW Drive Unit
- CARDIOHELP Base Unit
- CARDIOHELP-I
- Capacitive Level Sensor CLS with the accessory Level Sensor Pad LSP
- Flow-Bubble Sensor FBS
- Bubble Sensor BS
- Temperature Probe
- Venous Probe
- Heart-Lung Machine HL 20
- Pump modules for Heart-Lung Machine HL 20, Types: TPM, RPM
- Heater Unit HU 35
- Heater-Cooler Unit HCU 40
- Blood Monitoring Unit BMU 40
- Oxygenator QUADROX-iR * *
- Adult/Small Adult, microporous membrane
- Option: with integrated arterial filter
- HIT Set (Heparin-induced thrombocytopenia Set) Advanced 5.0 / 7.0 with SOFTLINE Coating
- HIT Set PLS Plus with SOFTLINE Coating
- Tubing Sets with Hemoconcentrators * *
- Tubing Sets with Centrifugal Pumps * *
- MECC Set * *
- Tubing Sets for CARDIOHELP-i * *
- Cardiac Intervention Set (CI Set)
- Organ Donor Perfusion Set (ODP Set) * *
- Minimized Extra Corporeal Circulation Set (MECC-i Set) *



Annex to the EC Certificate No. 50008-16-09

Revision status: 4

Valid from 2018-04-17 to 2020-07-09

Devices/device categories included in the certificate:

Medical Devices for the heart surgery, the intensive care and the cardiology

Class III:

- Temporary Pacing Electrode MYWIRE
- PLS Set (Permanent Life Support Set) / PLS Set Plus with BIOLINE Coating
- HLS Set (Heart-Lung Support Set) Advanced 5.0 / 7.0 with BIOLINE Coating

For the placing on the market of class III devices covered by this certificate an EC design-examination certificate according to directive 93/42/EEC annex II (4) is required.

* Products with or without BIOLINE Coating

Products with or without SOFTLINE Coating

Products with Bioline Coating are classified into class III

And J



Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2018-04-17
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerksstraße 16 * D-70565 Stuttgart * www.dekra-certification.de



CERTIFICATE

EN ISO 13485:2012 + AC:2012

DEKRA Certification GmbH hereby certifies that the company

Maquet Cardiopulmonary GmbH

Scope of certification:

Design and manufacturing, distribution and service of medical devices for the scopes heart surgery, intensive care, cardiology, and emergency medicine

Certified location:

Kehler Straße 31, 76437 Rastatt, Germany

(further locations see annex)

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 50008-Z6-00.

This certificate is valid from 2017-07-10 to 2020-07-09

Registration No.: 50008-11-02


Ruth Delbeck-Bayer

DEKRA Certification GmbH Stuttgart; 2017-06-27

 **DAKkS**

Deutsche
Akkreditierungsstelle
D-ZM-16029-08-00

Annex to the Certificate No. 50008-11-02

Revision status: 0

valid from 2017-07-10 to 2020-07-09

The following locations belong to the certificate above:

	Headquarters	Certified location	Scope of certification
	Maquet Cardiopulmonary GmbH	Kehler Straße 31 D-76437 Rastatt	Design, manufacturing, distribution and service of medical devices for the scopes heart surgery, intensive care, cardiology, and emergency medicine
	Subsidiaries	Certified locations	Scope of certification
1.	Maquet Cardiopulmonary GmbH	Kehler Straße 31 D-76437 Rastatt	Design, manufacturing, distribution and service of active medical devices for the scopes heart surgery, intensive care, cardiology, and emergency medicine Distribution of non-active medical devices for the scopes heart surgery, intensive care, cardiology, and emergency medicine
2.	Maquet Cardiopulmonary GmbH	Neue Rottenburger Straße 37 D-72379 Hechingen	Design and manufacturing of non-active medical devices for the scopes heart surgery, intensive care, cardiology, and emergency medicine



Ruth Delbeck-Bayer

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2017-06-27



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 16 02 11426 019

Manufacturer:**LISA laser products OHG**

Albert-Einstein-Str. 1-9
37191 Katlenburg-Lindau
GERMANY

**Facility(ies):**

LISA laser products OHG
Albert-Einstein-Str. 1-9, 37191 Katlenburg-Lindau, GERMANY

**Product
Category(ies):**

**Therapeutical solid state laser devices for
medical applications and related accessories;
Endoscopes and related instruments, adapters
and consumables**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

713073005_1

Valid from:

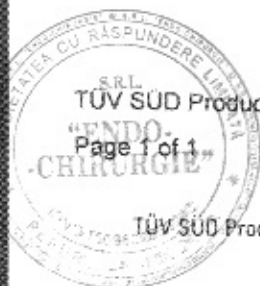
2016-04-11

Valid until:

2019-07-20

**Date,** 2016-04-11

Stefan Preiß



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 1

TÜV SÜD Product Service GmbH - Zertifizierstelle - Ridlerstraße 65 - 80339 München - Germany

TÜV®

Zertifizierungsvertrag

Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierungsordnung von TÜV SÜD Product Service.

Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierungsordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:

- Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben
- und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:
- Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.
- Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Certification contract

Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations.

On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuev-sued.de/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

Requirements for the validity of the certificate in principle:

- Validity of the quoted test standard(s)
- In addition for certificates with the right to use a certification mark and for QM certificates:
- Conditions for an adequate manufacturing are maintained
- Regular surveillance of the facility is performed.



Zertifizierungsstelle für Produkte / Certification Body for Products • e-mail ps-zert@tuev-sued.de
Zertifizierungsstelle für Medizinprodukte / Certification Body for Medical Devices • e-mail medical_devices@tuev-sued.de
Kundenservice / Clients Services • Phone +49/89/50 08-42 51 • Fax +49/89/50 08-42 30 • e-mail ps-zert@tuev-sued.de

Akkreditierungen / Benennungen (Status 14.10.2013) /
Accreditations / notifications (as of 2013-10-14)

Deutschland / Germany

Produktsicherheitsgesetz (ProdSG) /
Product Safety Act (ProdSG)

Europa / Europe

- * Niederspannungsrichtlinie 2006/95/EG
- * Spielzeugrichtlinie 2009/48/EG
- * Richtlinie für aktive medizinische Implantate 90/385/EWG
- * Richtlinie für Medizinprodukte 93/42/EWG
- * Richtlinie für In-vitro-Diagnostika 98/79/EG
- * Richtlinie für Gasverbrauchseinrichtungen 2009/142/EG
- * Richtlinie für persönliche Schutzausrüstungen 89/686/EWG
- * EMV-Richtlinie 2004/108/EG
- * Richtlinie für Sportboote 94/25/EG + 2003/44/EG
- * Richtlinie für Maschinen 2006/42/EG
- * Richtlinie für Ex-Schutz Geräte 94/9/EG
- * Low Voltage Directive 2006/95/EC
- * Toys Directive 2009/48/EC
- * Directive for Active Implantable Medical Devices 90/385/EEC
- * Directive for Medical Devices 93/42/EEC
- * Directive on In Vitro Diagnostic Medical Devices 98/79/EC
- * Directive for Gas Appliances 2009/142/EC
- * Directive for Personal Protective Equipment 89/686/EEC
- * EMC Directive 2004/108/EC
- * Directive for Recreational Craft 94/25/EC + 2003/44/EC
- * Directive for Machinery 2006/42/EC
- * Directive for Ex Safe Equipment 94/9/EC
- * ENEC Agreement for luminaires, household and IT equipment

USA

- * Nationally Recognized Testing Laboratory (NRTL) to 29 CFR 1910.7 by OSHA
- * Accredited for FDA 510(k) Third Party Review
- * Conformity Assessment Body to the MRA for Medical Devices; FDA QSR Reg Inspections, FDA 510(k) Third Party Review

Asien-Pazifik Region / Asia Pacific

- * Recognized Certification Body to Electrical Products (Safety) Regulation; Hong Kong
- * Konformitätsbewertungsstelle / Conformity Assessment Body to the MRA for Medical Devices; Australien / Australia
- * Konformitätsbewertungsstelle / Conformity Assessment Body to the MRA for Medical Devices; Neuseeland / New Zealand

Weltweit / Worldwide

- * NCB im CB-Scheme des IECCE / NCB in the CB Scheme of IECCE
- * ExCB im IECEx-Scheme des IECCE / ExCB in the IECEx Scheme of IECCE
- * Zertifizierungsstellen durch DAkkS akkreditiert
DE-ZE-11321-01, DE-ZM-11321-09 und DE-ZM-11321-01.
Certification Bodies accredited by DAkkS
DE-ZE-11321-01, DE-ZM-11321-09 and DE-ZM-11321-01.

CERTIFICATE



EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the company

Richard Wolf GmbH

Scope of certification:

Design and development, production, distribution, installation and service of systems, active medical devices (sterile, non-sterile), non-active medical devices (sterile, non-sterile) for human medicine, in particular for endoscopy and extracorporeal shockwave application

Design and development, production, and distribution of non-active implants in urology and surgery as well as accessories for processing (cleaning, disinfection, sterilization)

Certified location:

Pforzheimer Straße 32, 75438 Knittlingen, Germany

(further locations see annex)

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 50593-Z6U1-00.

This certificate is valid from 2019-04-01 to 2020-05-16

Registration No.: 50593-14-00

Ruth Delbeck-Bayer

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart, 2019-04-01

DEKRA Certification GmbH * Handwerksstraße 15 * D-70565 Stuttgart * www.dekra-certification.de



Deutsche
Akkreditierungsstelle
D-ZM-16029-08-00

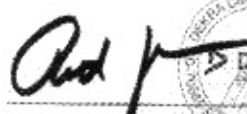
Annex to the Certificate No. 50593-14-00

Revision status: 0

valid from 2019-04-01 to 2020-05-16

The following locations belong to the certificate above:

	Headquarters	Certified location	Scope of certification
	Richard Wolf GmbH	Pforzheimer Straße 32 D-75438 Knittlingen, Germany	Design and development, production, distribution, installation and service of systems, active medical devices (sterile, non-sterile), non-active medical devices (sterile, non-sterile) for human medicine, in particular for endoscopy and extracorporeal shockwave application Design and development, production, and distribution of non-active implants in urology and surgery as well as accessories for processing (cleaning, disinfection, sterilization)
	Subsidiaries	Certified locations	Scope of certification
1.	Richard Wolf GmbH	Reuchlinstraße 10-11 D-10553 Berlin, Germany	Manufacture of flexible and rigid endoscopes


Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2019-04-01

DEKRA Certification GmbH * Handwerksstraße 15 * D-70565 Stuttgart * www.dekra-certification.de

EC CERTIFICATE

for the Quality Assurance System



**according the Directive 93/42/EEC,
Annex II excluding section (4)**

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company
Richard Wolf GmbH

Pforzheimer Straße 32, 75438 Knittlingen, Germany

Certified location:

Pforzheimer Straße 32, 75438 Knittlingen, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50593-Z6-00, the decision dated 2017-05-17 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2017-05-17 to 2020-05-16

Registration No.: 50593-16-04

Ruth Delbeck-Bayer

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart, 2017-05-17
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerkstraße 13 * D-70565 Stuttgart * www.dekra-certification.de



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zglg.de
ZLG-BG-295.10.02

Annex to the EC Certificate No. 50593-16-04

Revision status: 0

Valid from 2017-05-17 to 2020-05-16

Devices/device categories included in the certificate:

Class I s:

For the products listed below, review of the Quality Assurance System refers exclusively to aspects of manufacture concerned with securing and maintaining sterile conditions.

- Suction system filter, plume particulate

Class I m:

For the products listed below, the review of the Quality System refers exclusively to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

- Robotic surgical navigation system application software

Class II a:

- Basic endotracheal tube, reusable
- Basic roller pump
- Bone punch
- Bronchoscopy tube
- Cannulated surgical drill, reusable
- Endoscope assembly adaptor
- Endoscope leak tester, mechanical
- Endoscopic electrosurgical handpiece/electrode, bipolar, reusable
- Endoscopic electrosurgical handpiece/electrode, monopolar, reusable
- Endoscopic irrigation/aspiration pump
- Endoscopic needle, general-purpose, reusable
- ENT probe
- Flexible fiberoptic bronchoscope
- Flexible fiberoptic choledochoscope
- Flexible fiberoptic cystourethroscope
- Flexible fiberoptic hysteroscope
- Flexible fiberoptic nasopharyngoscope
- Flexible fiberoptic ureterorenoscope
- Flexible video bronchoscope, reusable
- Flexible video cystoscope, reusable
- Flexible video ureterorenoscope
- Fluted surgical drill, reusable
- Fluted surgical drill, single use, sterile
- General-purpose suction system, line-powered
- Haemorrhoid ligator
- High-pressure medical gas tubing
- Laparoscopic multi-instrument access port, reusable
- Laparoscopic multi-instrument access port, single-use
- Laparoscopic sleeve
- Laser lithotripsy system
- Line-powered surgical drilling system motor



Annex to the EC Certificate No. 50593-16-04

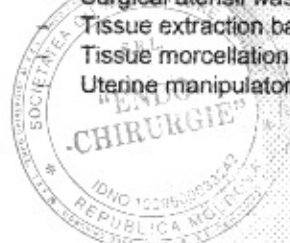
Revision status: 0

Valid from 2017-05-17 to 2020-05-16

Devices/device categories included in the certificate:

Class II a:

- Medical air low pressure tubing
- Microbial medical gas filter, sterile, single-use
- Operating room audiovisual data/device management system application software
- Orthopaedic burr, reusable
- Orthopaedic burr, single use
- Oscillating surgical saw blade, reusable
- Oscillating surgical saw blade, single use
- Particulate water purification filter
- Proctoscope, reusable
- Rectoscope
- Resectoscope
- Rigid bronchoscope
- Rigid cystourethroscope
- Rigid endoscopic cannula, reusable
- Rigid endoscopic cannula, single use
- Rigid endoscopic grasping forceps, reusable
- Rigid endoscope sheath
- Rigid endoscope telescope
- Rigid endoscope working guide
- Rigid hysteroscope
- Rigid intubation laryngoscope
- Rigid mediastinoscope
- Rigid nephroscope
- Rigid oesophagoscope
- Rigid optical laparoscope
- Rigid ureterorenoscope
- Rigid video laparoscope
- Sagittal surgical saw blade, reusable
- Sagittal surgical saw blade, single use
- Self-retaining surgical retraction system ring
- Spring-loaded pneumoperitoneum needle, reusable
- Stereotactic surgery system probe, reusable
- Suction cannula, reusable
- Suction system tubing
- Surgical drill chuck
- Surgical fluid/smoke waste management system suction unit
- Surgical gouge
- Surgical irrigation/aspiration handpiece, reusable
- Surgical irrigation/aspiration tubing set
- Surgical irrigation tubing set, single-use
- Surgical power tool system control unit, line-powered
- Surgical power tool system handpiece, rotary, pneumatic
- Surgical utensil washer/decontaminator
- Tissue extraction bag
- Tissue morcellation system
- Uterine manipulator



Annex to the EC Certificate No. 50593-16-04

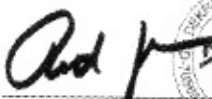
Revision status: 0

Valid from 2017-05-17 to 2020-05-16

Devices/device categories included in the certificate:

Class II b:

- Clip, surgical, suture
- Electrohydraulic lithotripsy system
- Electromechanical orthopaedic extracorporeal shock wave therapy system
- Electrosurgical system generator
- Endoscopic electrosurgical electrode, bipolar, single-use
- Endoscopic electrosurgical electrode, monopolar, reusable
- Endoscopic electrosurgical electrode, monopolar, single-use
- Endoscopic electrosurgical handpiece/electrode, bipolar, reusable
- Endoscopic electrosurgical handpiece/electrode, monopolar, reusable
- Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
- Gastrointestinal endoscopic insufflator
- Hysteroscopic irrigation/insufflation system
- Laser lithotripsy system
- Nasal snare, reusable
- Operating room audiovisual data/device management system
- Operating room audiovisual data/device management system application software
- Piezoelectric lithotripsy system
- Polymeric ureteral stent
- Ultrasonic lithotripsy system
- Ureteral stent-placement set



Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2017-05-17
Notified Body ID-number: 0124

DEKRA Certification GmbH * Hohenstauffenstraße 13 * D-70565 Stuttgart * www.dekra-certification.de

EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC, Annex V

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company
Richard Wolf GmbH

Pforzheimer Straße 32, 75438 Knittlingen, Germany

Certified location:

Pforzheimer Straße 32, 75438 Knittlingen, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex V for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50593-Z6-00, the decision dated 2017-05-17 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2017-05-17 to 2020-05-16

Registration No.: 50593-17-03



Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2017-05-17
Notified Body ID-number: 0124

DEKRA Certification GmbH, Handwerkerstraße 15 • D-70565 Stuttgart • www.dekra-certification.de



Benannt durch/Designated by
Zentralstelle der Länder
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bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Annex to the EC Certificate No. 50593-17-03

Revision status: 0

Valid from 2017-05-17 to 2020-05-16

Devices/device categories included in the certificate:

Class I s:

For the products listed below, review of the Quality Assurance System refers exclusively to aspects of manufacture concerned with securing and maintaining sterile conditions.

- Endoscope assembly adaptor
- Endoscope inflation bulb
- Flexible bronchoscopic biopsy forceps, reusable
- Flexible endoscopic cytology brush, single-use
- General-purpose ureteral catheter
- Proctoscope, single-use
- Rigid endoscope sheath
- Ureteropelvic balloon catheter
- Urinary stone retrieval basket, single-use

Class II a:

- Catheter introducer
- Endoscopic antifog solution
- Endoscopic needle, general-purpose, single-use
- Flexible bronchoscopic biopsy forceps, reusable
- General-purpose non-vascular guidewire

Ruth Delbeck-Bayer



Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2017-05-17
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerksstraße 15 * D-70565 Stuttgart * www.dekra-certification.de

CERTIFICATE



ISO 9001:2015

DEKRA Certification GmbH hereby certifies that the company

Richard Wolf GmbH

Scope of certification:

Design and development, production, distribution, sales, installation and service of systems, active medical devices (sterile, non sterile), non-active medical devices (sterile, non sterile), non-active implants, accessories for processing (cleaning, disinfection, sterilization, care) as well as endoscopes and accessories for industrial applications.

Certified location:

D-75438 Knittlingen, Pforzheimer Straße 32

Scope of certification:

Production of rigid endoscopes

Certified location:

D-10553 Berlin, Reuchlinstr. 10-11

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. A18071064.

This certificate is valid from 2018-09-12 to 2020-05-16

Certificate registration no.: 90714422/2

Lothar Weinhofen

Lothar Weinhofen
DEKRA Certification GmbH Stuttgart; 2018-09-12



Deutsche
Akkreditierungsstelle
D-M 16029-01-01