CERTIFICATE

EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

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-R2-00.

Certificate registration no.:	50593-14-02	Certificate valid from:	2021-11-29
Validity of previous certificate:	2021-11-28	Certificate valid to:	2024-11-28

DEKRA Certification GmbH Stuttgart Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2021-11-29

DAkkS Deutsche Akkreditierungsstelle D-ZM-16029-08-00

Digitally signed by Ghereg Victor
Date: 2024.07.03 08:49:51 EEST
Reason: MoldSign Signature
Location: Moldova

Annex to the Certificate No. 50593-14-02

Revision status: 0

valid from 2021-11-29 to 2024-11-28

The following locations / companies belong to the certificate above:

	Headquarter	Certified location	Scope of certification
	Richard Wolf GmbH	Pforzheimer Straße 32 75438 Knittlingen Germany	see page 1
	at the following locations / at the companies at the following locations		**Scope of certification**
1.	Richard Wolf GmbH	Reuchlinstraße 10-11 10553 Berlin Germany	Manufacture of flexible and rigid endoscopes

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2021-11-29

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-Z7-00, the decision dated 2020-04-01 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2020-04-01 to 2024-05-26

Registration No.: 50593-16-05

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15 • D-70565

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2020-04-01
Notified Body ID-number: 0124

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

34460

Annex to the EC Certificate No. 50593-16-05

Valid from 2020-04-01 to 2024-05-26

Revision status of the annex: 0 dated 2020-04-01

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.

- Endoscopic suction valve, single-use, sterile
- Suction system filter, plume particulate
- Suction/irrigation tubing, single use

Class II a:

- Basic endotracheal tube, reusable
- Basic roller pump
- Bone cutting forceps
- Bone graft funnel
- Bronchoscopy tube
- Cannulated surgical drill bit, reusable
- Endoscope assembly adaptor
- Endoscope sheath, reusable
- Endoscopic electrosurgical handpiece/electrode, bipolar, reusable
- Endoscopic electrosurgical handpiece/electrode, monopolar, reusable
- Endoscopic insufflation tubing set, single-use
- Endoscopic insufflation tubing set, sterile, reusable
- Flexible fibreoptic cystourethroscope
- Flexible fibreoptic hysteroscope
- Flexible fibreoptic nasopharyngoscope
- Flexible fibreoptic ureterorenoscope
- Flexible video bronchoscope, reusable
- Flexible video cystoscope, reusable
- Flexible video ureterorenoscope, reusable
- Fluted surgical drill bit, reusable
- General-purpose endoscopic needle, reusable
- General-purpose endoscopic needle, single-use
- Haemorrhoid ligator
- High-pressure medical gas tubing
- Laparoscopic access cannula, reusable
- Laparoscopic multi-instrument access port, reusable
- Laparoscopic multi-instrument access port, single-use
- Laser fibre
- Line-powered surgical power tool system motor
- Medical air low pressure tubing
- Microbial medical gas filter, sterile, single-use
- Operating room audiovisual data/device management system application software
- Orthopaedic bur, reusable
- Orthopaedic bur, single-use
- Resectoscope
- Rigid bronchoscope
- Rigid cystourethroscope
- Rigid endoscope telescope
- Rigid endoscopic grasping forceps, reusable
- Rigid optical hysteroscope
- Rigid intubation laryngoscope, reusable

Annex to the EC Certificate No. 50593-16-05

Valid from 2020-04-01 to 2024-05-26

Revision status of the annex: 0 dated 2020-04-01

Devices/device categories included in the certificate:

- Rigid mediastinoscope
- Rigid nephroscope
- Rigid optical laparoscope
- Rigid ureterorenoscope
- Spinal needle, single-use
- Spring-loaded pneumoperitoneum needle, reusable
- Surgical drill guide, reusable
- Surgical fluid/smoke waste management system suction unit
- Surgical guillotine
- Surgical irrigation tubing set, reusable
- Surgical irrigation tubing set, single-use
- Surgical irrigation/aspiration handpiece, reusable
- Surgical irrigation/aspiration tubing set
- Surgical power tool system control unit, line-powered
- Tissue extraction bag
- Tissue morcellation system
- Tissue morcellation system handpiece, line-powered
- Uterine manipulator cervical cup/transilluminator
- Uterine manipulator, reusable
- Uterine probe

Class II b:

- Electrosurgical system generator
- Endoscopic electrosurgical electrode, bipolar, reusable
- Endoscopic electrosurgical electrode, bipolar, single-use, sterile
- Endoscopic electrosurgical handpiece/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
- General/multiple surgical diode Laser system
- Hysteroscopic irrigation/insufflation system
- Laparoscopic insufflator
- Laser lithotripsy system
- Operating room audiovisual data/device management system application software
- Piezoelectric lithotripsy system
- Soft-tissue/mesh anchor, non-bioabsorbable
- Ultrasonic lithotripsy system
- Electromechanical orthopaedic extracorporeal shock wave therapy system

DEKRA Certification GmbH D-70565 Stuttgart, Handwerkstraße 15 DEKRA DEKRA Certification

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-04-01
Notified Body ID-number: 0124

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-Z7-00, the decision dated 2020-04-01 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2020-04-01 to 2024-05-26

Registration No.: 50593-17-04

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15, D-70565

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2020-04-01
Notified Body ID-number: 0124

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

84460

Annex to the EC Certificate No. 50593-17-04

Valid from 2020-04-01 to 2024-05-26

Revision status of the annex: 0 dated 2020-04-01

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 inflation bulb
- Proctoscope, single-use
- Rectoscope, single-use

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15 D-70565

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-04-01
Notified Body ID-number: 0124

Suction and irrigation tube set, sterile

NOTE

Refer to instructions for use GA-B 145 for suction and irrigation handle 8385.901!

Technical description:

1. With coupler to connect to suction and irrigation handle 8385.901
   - ⇨ Blue color coding for irrigation
   - ⇨ Gray color coding for suction
2. Irrigation tube for connecting to suitable irrigation containers or irrigation pumps. With various connectors:
   - ⇨ Luer-Lock
   - ⇨ Piercing spike
   - ⇨ SAFE-LOCK®
3. Suction tube for connecting to a collection or secretion container and/or vacuum pump.

Intended use

The suction and irrigation tube set is used in conjunction with the corresponding suction and irrigation handle (incl. its accessories, e.g. suction and irrigation tubes) for clearing the operating field and aspirating blood, secretion, irrigation fluid and smoke.

Indications and field of use

Diagnostics and/or therapy in connection with endoscopic accessories in minimally invasive surgical applications in the various medical disciplines (surgery, urology, thoracoscopy or gynecology)

This product is intended exclusively for use by medical experts and may only be used by adequately qualified and trained medical personnel.

Contraindications and side effects

There are currently no known contraindications directly related to the product. On the basis of the patient's general condition, the attending physician must decide whether or not the intended use is possible.

When used as intended, there are no known side effects.

RICHARD WOLF GmbH
Pforzheimer Straße 32
75438 Knittlingen

Combinations

⚠ CAUTION

Incorrect product combinations!

Injuries to the patient, user, or others, as well as damage to the product are possible.

Different products may only be combined if the intended use and the relevant technical data (working length, diameter, peak voltage, etc.) are the same.

The instruction manuals of the products used in combination with this product must be observed.

The suction and irrigation tube set is used in conjunction with the suction and irrigation handle 8385.901 and suitable irrigation containers, pumps and collection or secretion containers.

Additional guidance for use

⚠ WARNING

Reprocessing of disposable items!

The service life of the products labeled as disposable items is limited to a single use on a single patient.

Reprocessing of disposable items for further use can impair and/or change the product properties and therefore endanger patients, users, and others.

Possible hazards / risk factors:

▷ Stability problems
▷ Damage to the product
▷ Significant functional impairments
▷ Highly increased risk of infection
▷ Biocompatibility problems

When reprocessing a disposable item, the product responsibility lies with the user or reprocessor.

In this case, the safety and performance can no longer be guaranteed by the manufacturer.

Illustration

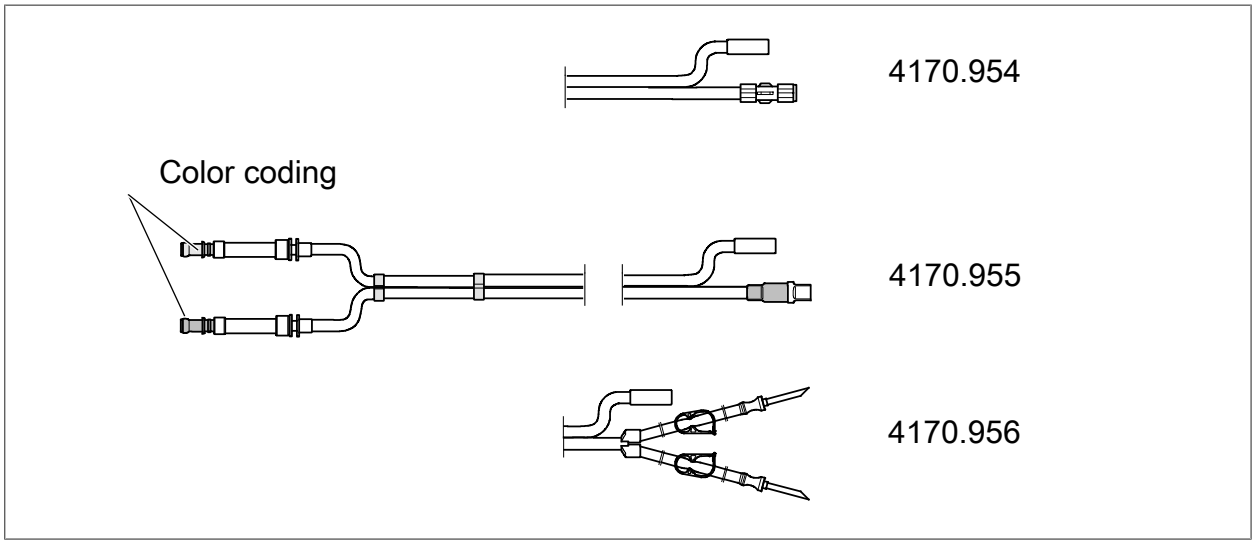


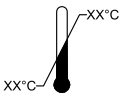
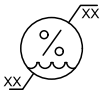
Fig. 1

Item number	Description
4170.954	**Irrigation tube**: With Luer-Lock, for connection to the irrigation tube of a suction and irrigation tube set, e.g., irrigation tube of the Endo-Irrigator 2211 **Suction tube**: For connection to a collection or secretion container and/or vacuum pump. **Tube length**: 3 meters
4170.955	**Irrigation tube**: With SAFE-LOCK®, for connection to an irrigation container. **Suction tube**: For connection to a collection or secretion container and/or vacuum pump. **Tube length**: 3 meters
4170.956	**Irrigation tube**: With 2 piercing spikes, for connection to an irrigation container. **Suction tube**: For connection to a collection or secretion container and/or vacuum pump. **Tube length**: 3 meters

8.1 Labeling

Symbols	Designation
	Follow the manual
	Caution
	Product number
	Lot code
	Manufacturer
	Manufacturing date
	Number, amount

RICHARD WOLF GmbH
Pforzheimer Straße 32
75438 Knittlingen

Symbols	Designation
	Expiry date
STERILE EO	Sterilized with ethylene oxide
	Single sterile barrier system with protective packaging inside (sterilized using ethylene oxide)
	Do not reuse!
	Do not resterilize
	Keep away from sunlight!
	Store in a dry place!
	Temperature, limitation
	Humidity, limitation
	Do not use if package is damaged
PHT DEHP	Contains phthalates or phthalates are present: diethylhexylphthalate (DEHP)
CE	CE marking in accordance with Medical Devices Directive 93/42/EEC. **Applies only** if the **product and/or packaging bears this marking**. Products in Class IIa and higher and sterile products or products with a measuring function in Class I are also marked with the four-digit identification number of the notified body.

Operating, storage, transport, and shipping conditions

Disposable items, sterile products	Follow the instructions on the packaging!

ATTENTION

Store sterile products in their original packaging until use.
Improper storage can lead to loss of sterility.

ATTENTION

The relevant regulations and laws valid in the country of use must be observed when disposing of the product.
▷ For further information, please contact the manufacturer.