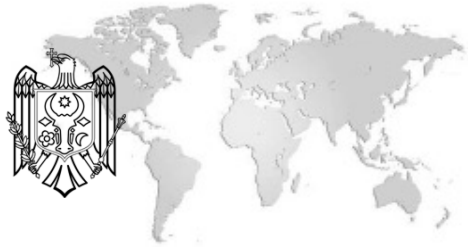
EC CERTIFICATE

for the Quality Assurance System

Digitally signed by Ghereg Victor
Date: 2024.02.27 14:50:15 EET
Reason: MoldSign Signature
Location: Moldova



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 Stuttgart

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

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 * Stuttgart, Handwerkstraße 15 * D-70565

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

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

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

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

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

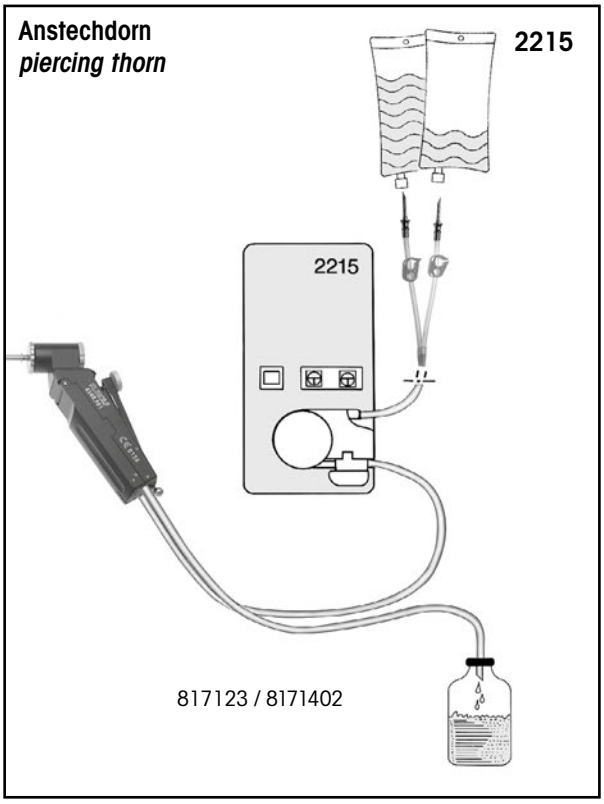
Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2021-11-29

Suction-Irrigation Tube Sets

Saug-Spül-Schlauchsets

Reusable

Mehrmalgebrauch

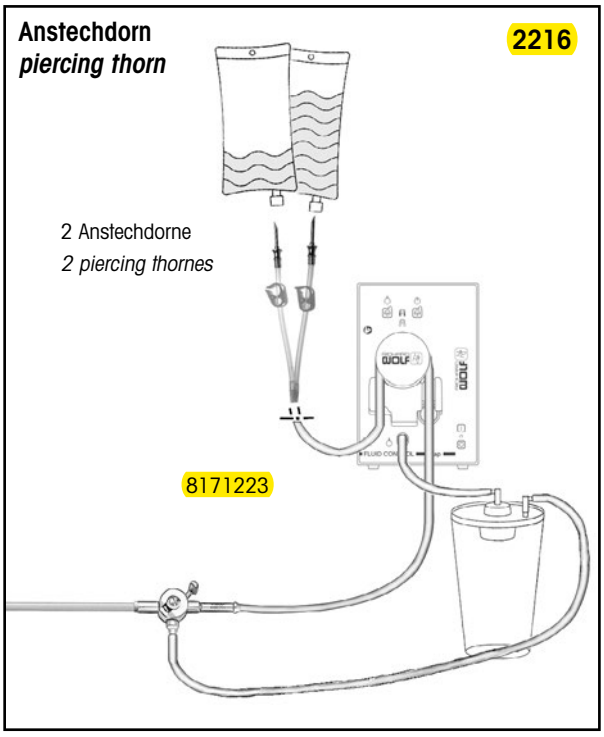


Schlauchansatz
mit Luer-Lock-Anschluss,
für Saug-Spül-Handgriff 8385.901
und Schlauchset 8171223 oder 8170.223,
wiederverwendbar 817123

Saugschlauch
3 m, für Saug-Spül-Handgriff 8385.901,
wiederverwendbar 8171402

Tube attachment
with luer-lock connector,
for suction-irrigation handle 8385.901
and tube set 8171223 or 8170.223,
reusable 817123

Suction tube
3 m, for suction-irrigation handle 8385.901,
reusable 8171402



Schlauchset mit Anstechdorn,
mit Luer-Lock Anschluss,
autoklavierbar, incl. 10 Ersatzmembranen, wiederverwendbar
für 20 Aufbereitungszyklen,
für FLUID CONTROL LAP 2216 8171223

Tubing set with piercing connector,
with luer-lock connector,
autoclavable, incl. 10 replacement membranes,
reusable for 20 reprocessing cycles,
for FLUID CONTROL LAP 2216 8171223

Vakuum-Schlauch
von Pumpe zu Sekretbehälter 8170.401

Vacuum tube
from pump to secretion trap 8170.401

8

Lot : 32

RICHARD WOLF
spirit of excellence

INSUFFLATOR HIGHFLOW 45 EVAC

WITH SMOKE GAS EVACUATION

		Product no.
Insufflator 45 EVAC bndl consisting of: Insufflator 45 EVAC FR 45 l/min (2235011), Insufflation tube set L 2.5 m (8170.101), Hygiene filter, sterile, disposable (PACK= 10 PCS) (4171.111), Insufflation tube set L 2.7 m with integrated hygiene filter, sterile, disposable (PACK= 10 PCS) (4170.501) Smoke gas evacuation tube set L 2.7 m, sterile, disposable (PACK= 10 PCS) (4170503) Footswitch with 1 pedal (20301031) and power cable, 3 m long (2440.03)		**22350111**
Accessories: Tube sets for insufflation		
Smoke gas evacuation tube set L 2.7 m, sterile, disposable (PACK= 10 PCS)		**4170503**
Accessories for gas supply		
CO_2 connection tube 1.5 m NIST-NIST		**74021038**
with		
Pressure reducer for CO_2 connector DIN 477-1	DIN 477-1	**74007054**
Pressure reducer for CO_2 connector DIN EN ISO 407	DIN EN ISO 407	**74007055**
Pressure reducer for CO_2 connector ISO 5145	ISO 5145	**74007056**
or		
Connection tube for CO_2 5.0 m DIN for centralized CO_2 gas supply (Dräger)		**74021039**
Connection tube for CO_2 5.0 m NF for centralized CO_2 gas supply (Liquid Air)		**74021040**
Software modules (optional)		
Software module CAN bus CAN bus interface for integration in CORE		**2235101**
Software module BABY MODE BABY MODE for special use in pediatrics		**2235102**
Software module VIDEO DISPLAY: video display using DIALOG via CAN bus		**2235103**