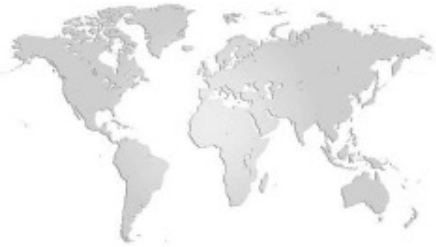
EC CERTIFICATE

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

Digitally signed by Dubalari Pavel
Date: 2022.05.05 12:07:17 EEST
Reason: MoldSign Signature
Location: Moldova

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-Z7-00.

Certificate registration no.:	50593-14-01	Certificate valid from:	2020-04-01
Validity of previous certificate:	2020-03-31	Certificate valid to:	2023-03-31

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

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

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-04-01

Annex to the Certificate No. 50593-14-01

Revision status: 0

valid from 2020-04-01 to 2023-03-31

The following locations / companies belong to the certificate above:

	Headquarter	Certified location	Scope of certification
	Richard Wolf GmbH	Pforzheimer Straße 32 75438 Knittlingen Deutschland	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 Deutschland	Manufacture of flexible and rigid endoscopes

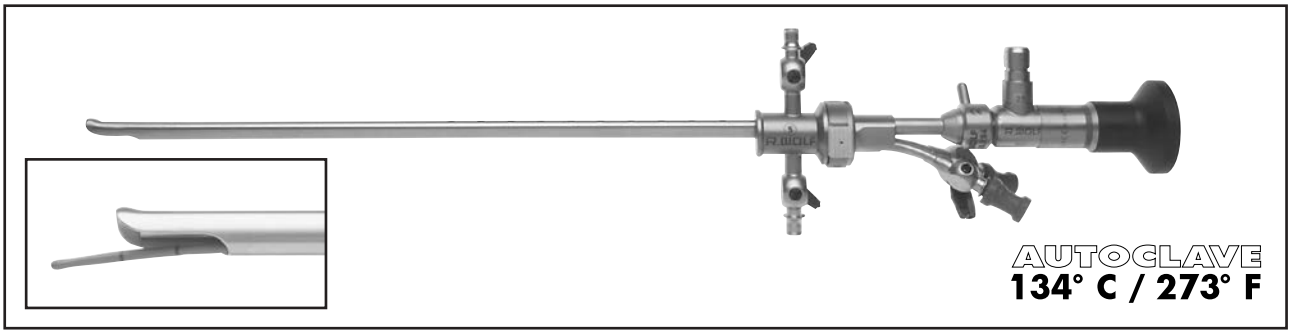
Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-04-01

Lot: 19

RICHARD WOLF
spirit of excellence

Cysto-Urethroscope
8650 e-line
for telescope 4 mm, 0°, 12°, 30°, 70°
and adaptors

Cysto-Urethroskop
8650 e-line
für Optik 4 mm, 0°, 12°, 30°, 70°
und Ansätze



3

Schäfte und Obturatoren *Sheaths and obturators*						Ansätze Adaptors		
								
Schaft inkl. Obturator *Sheath incl. obturator*	Schaft einzeln *Sheath single*	Obturator einzeln *Obturator single*	Charr. *Fr.*	Kennfarbe *Colour code*	Durchlass in Charr. *Capacity (Fr.)*	nur zur Diagnostik *only for examination*	1 Einführungshahn *1 Instrument port*	2 Einführungshähne *2 Instrument ports*
8650.0141	**8650.0145**	**8650.0147**	16	gelb *yellow*	1x5*	**8650.254**	**8650.264**	**8650.284**
8650.0241	**8650.0245**	**8650.0247**	17.5	grün *green*	1x5 oder / *or* 2x4			
8650.0341	**8650.0345**	**8650.0347**	19.5	rot *red*	1x7 oder / *or* 2x5			
8650.0441	**8650.0445**	**8650.0447**	21	blau *blue*	1x10 oder / *or* 2x6			
8650.0541	**8650.0545**	**8650.0547**	23	weiß *white*	1x12 oder / *or* 2x7			
8650.0641	**8650.0645**	**8650.0647**	25	schwarz *black*	1x15			

* *for urethroscopy (cystoscopy for diagnosis only with adaptor 8650.254)*

* nur urethroskopisch (cystoskopisch nur zur Diagnostik geeignet über Ansatz 8650.254)

Sicht-Obturatoren siehe Seite / *Viewing obturators see page D 9*

Ø	Blickrichtung *Viewing direction*	Typen *Types*	PANOVIEW-Optiken *PANOVIEW telescopes*
4 mm	0°	**8650.414 / PDD blue 8650.514**	 HD High Definition
	12°	**8654.431 / PDD blue 8650.531**	
	30°	**8654.422 / PDD blue 8654.522**	
	70°	**8650.415 / PDD blue 8650.515**	

Accessories:
***Fiber light cable set**, Ø 2.5 mm, 2.3 m long consisting of:*
Fiber light cable (80662523), adapter projector side (8095.07) and adapter endoscope side (809509) 806625231
*For sterilising: **Telescope reprocessing basket**, capacity 1 telescope 38021.111*

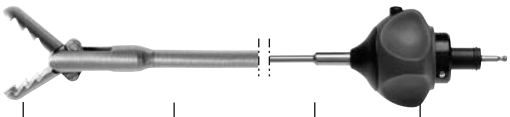
Zubehör:
Fiber Lichtleiter Set, Ø 2,5 mm, 2,3 m lang bestehend aus:
Fiber Lichtleiter (80662523), Adapter projektorseitig (8095.07) und Adapter endoskopseitig (809509) 806625231
Zur Aufbereitung: **Optik-Aufbereitungskorb**, Aufnahmekapazität 1 Endoskop 38021.111

Rigid accessory instruments

Micro Modular System HySafe
360° rotatable, flushable, easy click

Starre Hilfsinstrumente

Kleinmodulares System HySafe
360° drehbar, durchspülbar, easy click

Maulteil / *Insert with sheath* 	Einsatzempfehlung *Recommended fields of application*	Typen / *Types*	Charr. / *Fr.*	NL / WL	Griff mit Überlastschutz *Handle with overload protection* 	**Komplett-Instrument** • **Maulteil** • **Griff** ***Complete instrument*** • ***Insert with sheath*** • ***Handle*** Typen / *Types*
Biopsiezange ***Biopsy forceps*** 	Uretero-Renoskopie *Uretero-renoscopy*	8952.6008	5	550	8083.001	**8952.6002**
Fasszange mit Mauszahn ***Grasping forceps*** *with mouse jaws* 		8952.6118	4	550		**8952.6112**
		8952.6218	5	550		**8952.6212**
Fasszange mit Hechtmaul ***Grasping forceps*** *with alligator jaws* 		8954.6808	5	550		**8954.6802**
Fasszange mit Hechtmaul ***Grasping forceps*** *with alligator jaws* 		8952.6508	5	550		**8952.6502**

11

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

schülke

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
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:

Disinfectant for medical devices, wound care products and gel as listed in 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.	004567 MR2
Certificate unique ID	170742365
Effective date	2020-06-09
Expiry date	2023-12-18
Frankfurt am Main	2020-06-09

DQS Medizinprodukte GmbH

Sigrid Uhlemann
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.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 004567 MR2
Certificate unique ID: 170742365
Effective date: 2020-06-09

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

Device	Class
acryl-des® Gebrauchslösung	IIa
acryl-des® Desinfektionstücher	IIa
antifect® AF (N)	IIa
antifect® N liquid	IIa
antifect® extra	IIa
aspirmatic®	IIa
boots wound healing gel	IIb
dentavon®	IIa
dentavon® liquid	IIa
Essential+ Wipes	IIa
gigasept® AF	IIb
gigasept® AF forte	IIb
gigasept® FF (neu)	IIb
gigasept® Instru AF	IIb
gigasept® med	IIb
gigasept® pearls	IIb
gigasonic®	IIb
gigazyme® Xtra	IIb
mikrozid® AF liquid	IIa
mikrozid® AF wipes	IIa
mikrozid® alcohol free liquid	IIa
mikrozid® alcohol free wipes jumbo	IIa
mikrozid® liquid	IIa
mikrozid® PAA wipes	IIb
mikrozid® sensitive liquid	IIa
mikrozid® sensitive wipes	IIa
mikrozid® universal liquid	IIa
mikrozid® universal wipes	IIa
mikrozid® wipes	IIa
mucalgin®	IIa
mucadont® IS	IIb
mucapur® CD	IIa
mucocit® T	IIb
octenilin® wound gel	IIb
octenilin® wound irrigation solution	IIb
octenisan® md nasal gel	IIa
octenisept® Gel	IIb
octenisept® wound gel	IIb

Annex to certificate
Certificate registration No.: 004567 MR2
Certificate unique ID: 170742365
Effective date: 2020-06-09

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

Device	Class
perform®	IIa
pursept® AF	IIa
pursept® A Xpress liquid	IIa
pursept® A Xpress wipes	IIa
quartamon® med	IIa
rotasept®	IIb
septinol® SA	IIa
terralin® liquid	IIa
terralin® protect	IIa
thermosept® ED	IIb
thermosept® NDR	IIa
TPH® protect	IIa
SteraClar Daily	IIa
SteraDif Powder	IIa
SteraPex	IIb
SteraPex Rotary	IIb
SteraClens Alcohol Free	IIa
SteraClens	IIa
SteriWipe+ Alcohol Free	IIa
SteriWipe+	IIa
DESIMATIC-ID PLUS	IIb
DESIFOR-ONE multi wipes	IIa
DESIFOR-ONE PROTECT	IIa
B3	IIa

CERTIFICATE

This is to certify that the company

schülke

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

with the organizational units/sites as listed in the annex

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

Scope:
Development, production and sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.

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:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	004567 MP2016
Certificate unique ID	170774693
Effective date	2021-06-27
Expiry date	2024-06-26
Frankfurt am Main	2021-06-27

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
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

410.90.en Version 1.0

Annex to certificate
Certificate registration No.: 004567 MP2016
Certificate unique ID: 170774693
Effective date: 2021-06-27

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

Location	Scope
Schülke & Mayr GmbH Robert-Koch-Straße 2 22851 Norderstedt Germany	Development, production and sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.
Schülke & Mayr AG Sihlfeldstrasse 58 8003 Zürich Switzerland	Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.
Schülke & Mayr Ges. m. b. H. Seidengasse 9 1070 Wien Austria	Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.
Schülke France S.A.R.L. 50 boulevard National 92250 La Garenne France	Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.
Schülke & Mayr UK Ltd. Cygnet House, 1 Jenkin Road, Meadowhall Sheffield, S9 1AT United Kingdom	Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.
Schülke & Mayr Benelux B.V. Oudeweg 8d 2031 CC Haarlem Netherlands	Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.
Schulke Polska Sp. z o.o. Eurocentrum Office Complex Budynek Delta al. Jerozolimskie 132 02-305 Warszawa Poland	Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.

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