

# 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

*Ruth Delbeck-Bayer*



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

DEKRA Certification GmbH \* Handwerkstraße 15 \* D-70565 Stuttgart \* [www.dekra-certification.de](http://www.dekra-certification.de)



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://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

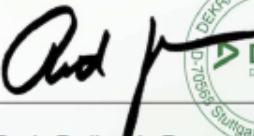
Revision status of the annex: 0 dated 2020-04-01

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

  
Ruth Delbeck-Bayer



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

DEKRA Certification GmbH \* Handwerkstraße 15 \* D-70565 Stuttgart \* [www.dekra-certification.de](http://www.dekra-certification.de)

# 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).

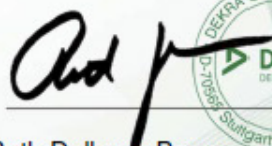
### Certified location:

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 |

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



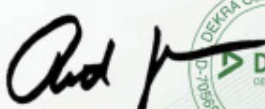
# Annex to the Certificate No. 50593-14-01

Revision status: 0

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

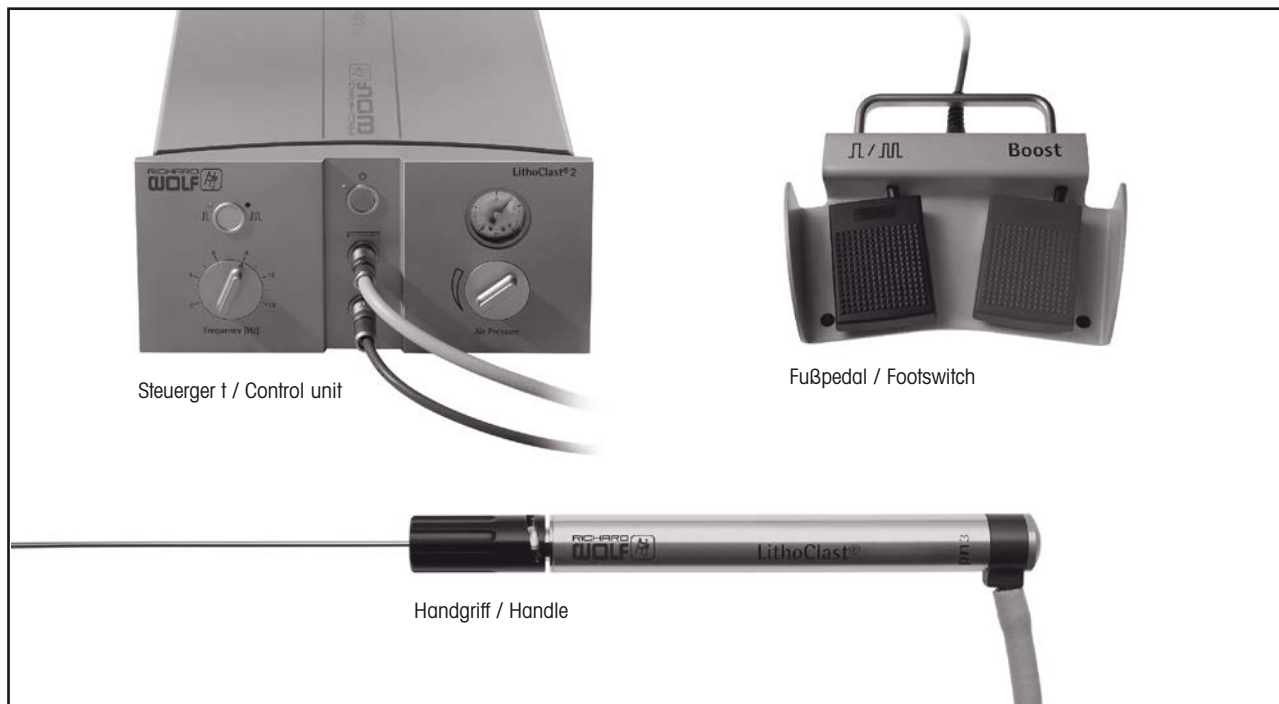
The following locations / companies belong to the certificate above:

|    | Headquarter                                                              | Certified location                                        | Scope of certification                       |
|----|--------------------------------------------------------------------------|-----------------------------------------------------------|----------------------------------------------|
|    | Richard Wolf GmbH                                                        | Pforzheimer Straße 32<br>75438 Knittlingen<br>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<br>10553 Berlin<br>Deutschland       | Manufacture of flexible and rigid endoscopes |



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



*LithoClast 2**LithoClast 2 set**LithoClast 2**LithoClast 2-Set***LithoClast 2 set**

consisting of:

Control unit (2292001), electric footswitch (2292871), spare tube (8175.715), connector for air outlet (2292889), Richard Wolf pneumatic handle pn3 (8745310), adapter spacer (8745.212), probe cap (8745.332), compressed air tube (8175.711), probe guides (8742.051), silicone seals (4745.976), transport case (2295.201), LithoVac Iv3 base section (8745103), silicone suction tube (8745.106),

LithoClast probe, Ø 2 mm, length 425 mm (8742.004),

LithoClast probe, Ø 1 mm, length 605 mm (8742.002),

LithoClast probe, Ø 0.8 mm, length 605 mm (8742.001),

LithoClast probe, Ø 1.6 mm, length 605 mm (8742.003),

LithoClast probe, Ø 0.8 mm, length 668 mm

for suction tube Ø 1.6 mm (8742.012),

suction tube, Ø 4 mm, length 353 mm (8745.194),

suction tube, Ø 3.5 mm, length 380 mm (8745.193),

suction tube, Ø 1.6 mm, length 595 mm (8745.192),

stone catcher (2295.510), sterile, pack of 10, stone catcher holder

(2292025), compressed air tube with Dräger connector (2295.811),

power cable, European connector (2292850),

fuses (2292880) ..... 2292005

Sets with other power cables or compressed air tubes on request.

**LithoClast 2 Set**

bestehend aus:

Steuergerät (2292001), elektrisches Fußpedal (2292871), Ersatzschlauch (8175.715), Anschlussstück für Luftauslass (2292889), Richard Wolf pneumatisches Handstück pn3 (8745310), Einstell-Zwischenstück (8745.212), Sondenkappe (8745.332), Druckluftschlauch (8175.711), Sondenführungen (8742.051), Silikon-dichtungen (4745.976), Transportkoffer (2295.201), LithoVac Iv3 Grundkörper (8745103), Silikon Saugschlauch (8745.106),

LithoClast Sonde, Ø 2 mm, Länge 425 mm (8742.004),

LithoClast Sonde, Ø 1 mm, Länge 605 mm (8742.002),

LithoClast Sonde, Ø 0,8 mm, Länge 605 mm (8742.001),

LithoClast Sonde, Ø 1,6 mm, Länge 605 mm (8742.003),

LithoClast Sonde, Ø 0,8 mm, Länge 668 mm

für Saugrohr Ø 1,6 mm (8742.012),

Saugrohr, Ø 4 mm, Länge 353 mm (8745.194),

Saugrohr, Ø 3,5 mm, Länge 380 mm (8745.193),

Saugrohr, Ø 1,6 mm, Länge 595 mm (8745.192),

Steinfänger (2295.510), steril, VE = 10 Stück, Steinfängerhalter

(2292025), Druckluftschlauch mit Dräger Anschluss (2295.811),

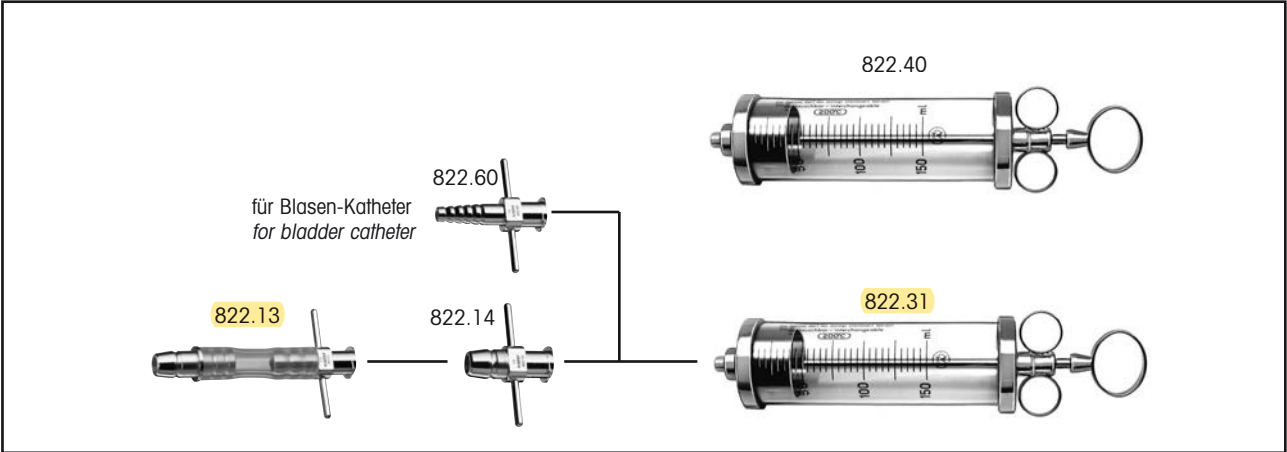
Netzkabel, Europ. Anschluss (2292850),

Sicherungen (2292880) ..... 2292005

Sets mit anderen Netzkabeln oder Druckluftschläuchen auf Anfrage.

Bladder Syringe

Blasenspritzen



|                                                                                                               | Ø     | ml  | Ersatz-Zylinder<br>Spare barrel | Typen<br>Types |
|---------------------------------------------------------------------------------------------------------------|-------|-----|---------------------------------|----------------|
| <b>Blasenspritze</b> für flexible und starre Ansätze<br><b>Bladder syringe</b> for flexible or rigid adapters | 54 mm | 150 | 82295                           | <b>822.31</b>  |
| <b>Ansatz</b> zum flexiblen Ansetzen der Spritze<br><b>Adapter</b> for flexible connection of syringe         |       |     |                                 | <b>822.13</b>  |
| <b>Ansatz</b> zum starren Ansetzen der Spritze<br><b>Adapter</b> for rigid connection of syringe              |       |     |                                 | <b>822.14</b>  |
| <b>Ansatz starr</b> für Blasenspritze<br><b>Rigid adapter</b> for bladder syringe                             |       |     |                                 | <b>822.60</b>  |
| <b>Blasenspritze</b><br><b>Bladder syringe</b>                                                                | 54 mm | 150 | 82295                           | <b>822.40</b>  |
| <b>Adapter</b> für Toomey-Spritze, mit Kegel<br><b>Adapter</b> for Toomey syringes, with cone                 |       |     |                                 | <b>845.11</b>  |