

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



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

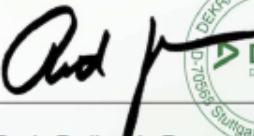
Revision status of the annex: 0 dated 2020-04-01

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


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

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).

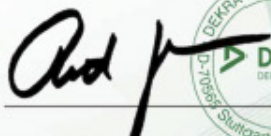
Certified location:

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



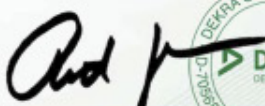
Annex to the Certificate No. 50593-14-01

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 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



PANOVIEW Telescopes

Overview

PANOVIEW-Optiken

Übersicht

Blickrichtung Viewing direction	Farbkodierung Colour code	Anwendung Application	Ø mm	 AUTOCLAVE 134° C / 273° F	
0°	 blau blue	Standard	4	8650.414	
		PDD blue	4	8650.514**	
		schwachkalibrig small calibre	3.3	8660.424	
12°	 orange orange	Standard	4	8654.431	
		PDD blue	4	8654.531**	
30°	 rot red	Standard	4	8654.422	
		PDD blue	4	8654.522**	
		schwachkalibrig small calibre	3.3	8656.422	
		Langschaft Long sheath	4	8668.433*	
70°	 gelb yellow	Standard	4	8650.415	
		PDD blue	4	8650.515**	

* Only 25° available.

** within the scope of our new, more powerful PDD system we have adapted our PANOVIEW telescopes to this blue PDD system.
To distinguish them, the PANOVIEW telescopes are marked with the word **blue** and can of course also be used in conjunction with your previous PDD system.

* Nur in 25° erhältlich.

** im Rahmen unseres neuen, leistungsstärkeren PDD-Systems, haben wir unsere PANOVIEW-Optiken an dieses blue PDD-System angepasst.
Zur Unterscheidung sind die PANOVIEW-Optiken mit **blue** gekennzeichnet und können selbstverständlich auch mit Ihrem bisherigen PDD-System verwendet werden.

Electrodes

for resectoscopes, 4 mm telescope,
30°, 25°, 12°

Elektroden

für Resektoskope, Optik 4 mm,
30°, 25°, 12°

für Schaft for sheath		22 Charr. / Fr.	24 Charr. / Fr.	26 Charr. / Fr.	28 Charr. / Fr.
für Dauerspül-Schaft for continuous-irrigation sheath		24.5 / 25.5 Charr. / Fr.	26 / 27 Charr. / Fr.	28.9 Charr. / Fr.	
Großflächige Koagulations-Elektrode <i>Large coagulating electrode</i> 	Gabel Branches	blau / blue		weiß / white	
	Stiel Stem	rot / red		rot / red	
Kugel-Elektrode, tonnenförmig <i>Ball electrode, barrel-shaped</i> 	Gabel Branches	grün / green		8427.02 oder / or 8427.022*	
	Stiel Stem	rot / red		rot / red	
Rollen-Elektrode, tonnenförmig <i>Roller electrode, barrel-shaped</i> 	Gabel Branches	braun / brown		8423.02	
	Stiel Stem	rot / red		rot / red	
Koagulations-Elektrode <i>Coagulating electrode</i> 	Gabel Branches	blau / blue		8423.01	
	Stiel Stem	blau / blue		8423.09	
Haken-Elektrode <i>Hook electrode</i> 	Gabel Branches	blau / blue		weiß / white	
	Stiel Stem	rot / red		rot / red	
Messer-Elektrode nach Collins <i>Knife electrode by Collins</i> 	Gabel Branches	blau / blue		weiß / white	
	Stiel Stem	rot / red		rot / red	

* Electrode with guide stud for better stabilization. Suitable only for working elements with guide stud.

* Elektrode mit Führungsnase zur besseren Stabilisierung. Nur für Elektroden-Arbeits-Element mit Führungsschlitze geeignet.

EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company

UROMED Kurt Drews KG
Meessen 7/11
22113 Oststeinbek
Germany

with locations listed in the appendix

has introduced, applies and maintains a quality assurance system
**for the aspects of manufacture concerned with securing and maintaining
sterile conditions**

for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the
Council Directive 93/42/EEC was verified by an audit:

Annex V

This certification is subject to surveillance by MEDCERT.

Effective date: 2020-03-12
Expiry date: 2024-05-27

Report No.: 1202FS27F
Process No.: QS – 1202
Certificate No.: 1202GB415200310

Hamburg, 2020-03-10

MEDCERT Certification Body
(Markus Bianchi)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482



Appendix of EC Certificate of Conformity

Process No.: QS – 1202

Certificate No.: 1202GB415200310

List of locations included in the scope of certificate

Meessen 9
22113 Oststeinbek
Germany

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482



Appendix of EC Certificate of Conformity

Process No.: QS – 1202

Certificate No.: 1202GB415200310

List of products / product categories included in the scope of certificate**Medical devices for Urology**

- Catheters
- Catheter accessories
- Urine-drainage systems

– End of list –

This appendix is integral part of the above-referenced certificate.
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To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482



EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company:

UROMED Kurt Drews KG
Meessen 7/11
22113 Oststeinbek
Germany

with locations listed in the appendix

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II without section 4

This certification is subject to surveillance by MEDCERT.

Effective date: 2020-03-12
Expiry date: 2024-05-27

Report No.: 1202FS27F
Process No.: QS – 1202
Certificate No.: 1202GB410200310

Hamburg, 2020-03-10

MEDCERT Certification Body
(Markus Bianchi)

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MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



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ZLG-BS-237.10.15

Appendix of EC Certificate of Conformity

Process No.: QS – 1202

Certificate No.: 1202GB410200310

List of locations included in the scope of certificate

**Meessen 9
22113 Oststeinbek
Germany**

– End of list –

This appendix is integral part of the above-referenced certificate.
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MEDCERT Identification Number: 0482



Appendix of EC Certificate of Conformity

Process No.: QS – 1202

Certificate No.: 1202GB410200310

List of products / product categories included in the scope of certificate**Medical devices for Urology**

- **Biopsy guns**
- **Catheters**
- **Catheter sets**
- **Guide wires**
- **Stone retrieval baskets**
- **Cannulas**
- **Dilators**
- **Ureteral stents**

– End of list –

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ZLG-BS-237.10.15

Certificate

The certification body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company

UROMED Kurt Drews KG
Meessen 7/11
22113 Oststeinbek
Germany

with locations listed in the appendix

has introduced, applies and maintains a quality management system in the area of:

Design and development, manufacture, final inspection and distribution of medical devices for

- **Urology**
- **Gynecology**
- **Radiology**

The conformity of this quality management system to the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date: 2020-03-12

Expiry date: 2023-03-12

Report No.: 1202FS27F
Procedure No.: QS – 1202
Certificate No.: 1202GB445200310

Hamburg, 2020-03-10

MEDCERT Certification Body
(Markus Bianchi)

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MEDCERT is a DAKKS accredited management systems
certification body

Appendix of certificate

Procedure No.: QS – 1202

Certificate No.: 1202GB445200310

List of locations included in the scope of certificate

Meessen 9
22113 Oststeinbek
Germany

– End of list –

This appendix is integral part of the above-referenced certificate.
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MEDCERT is a DAkkS accredited management systems
certification body



Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00

UROMED CORAZOR Stanzbiopsie-Kanülen
UROMED CORAZOR Puncture Biopsy Cannulas

REF 6029 - 6031

Stanzbiopsie-Kanülen für CORAZOR
Mehrfach-Schussgeräte

Puncture biopsy cannulas for CORAZOR reusable biopsy instruments

Details mit großer Wirkung:

- passgenaues Einlegen der Kanüle
- sichere Fixierung
- stabile Führbarkeit der Kanüle
- bessere Kraftübertragung der Feder auf die Kanüle

Details with great effect:

- precise insertion of the cannula
- safe fixation of the cannula
- smooth guidance of the cannula
- increased power transmission between spring and cannula

Zur Biopsie und Entnahme von Weichgewebe

- Axial-Rotationsschliff für sehr gute Biopsatqualität
- optimale Führung durch hervorragende 3-Punkt-Fixierung der eingelegten Kanüle
- reibungsarme Führung durch spezielle Polierung – auch bei gebogener Kanülenführung
- mit Kanülenschutz zur Sicherheit vor Nadelstichverletzungen
- der Kanülenschutz unterstützt die Aufrechterhaltung der Sterilität
- Kontaminationsschutz durch verlängerten Kunststoffansatz
- einfaches Einlegen der Kanüle
- Probenkerbe 19 mm
- geeignet für ultraschallkontrollierte oder handgeführte Biopsie
- 1:1 Graduierung, alle 5 cm stärkere Graduierung

For biopsy and soft tissue sampling

- axial rotation cut for very high tissue results
- optimal guidance due to excellent 3-point fixation of inserted cannula
- smooth guidance by special polishing – even when cannula is bended
- with protective tube to avoid injuries by the needle
- the protective tube supports maintaining the sterility
- contamination protection by extended plastic attachment
- easy insertion of the cannula
- notch length 19 mm
- suitable for ultrasound or hand-guided biopsy
- 1:1 graduated, every 5 cm a thicker line

UROMED CORAZOR 3K|Trokar Stanzbiopsie-Kanüle
UROMED CORAZOR 3K|Trokar Puncture Biopsy Cannula

REF 6025

Einsatz mit CORAZOR Biopsie-Schussgerät in Halbautomatik

Using of CORAZOR biopsy device in semi-automatic

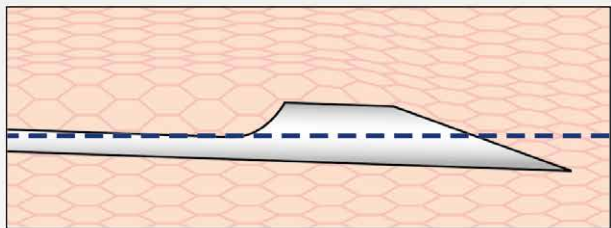
Zur Biopsie und Entnahme von Weichgewebe

- präzisere Karzinom-Diagnostik durch hohe Zielgenauigkeit des 3-kantigen Trokarschliffs
- 3-kantiger Trokarschliff und Probenkerbe für bestmögliche Aufnahme des Gewebes
- optimale Führung durch hervorragende 3-Punkt-Fixierung der eingelegten Kanüle
- reibungsarme Führung durch spezielle Polierung – auch bei gebogener Kanülenführung
- mit Kanülenschutz zur Sicherheit vor Nadelstichverletzungen
- der Kanülenschutz unterstützt die Aufrechterhaltung der Sterilität
- Kontaminationsschutz durch verlängerten Kunststoffansatz
- einfaches Einlegen der Kanüle
- Probenkerbe 19 mm
- geeignet für ultraschallkontrollierte Biopsie
- 1:1 Graduierung, alle 5 cm stärkere Graduierung

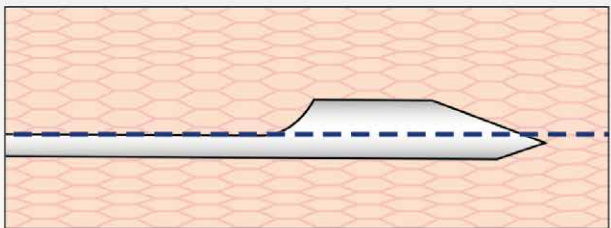
For biopsy and soft tissue sampling

- more precise diagnostic of carcinoma due to high point-exact sampling of tissue because of using triangular trocar shape
- best possible tissue sampling due to triangular trocar shape and sample notch
- optimal guidance due to excellent 3-point fixation of inserted cannula
- smooth guidance by special polishing – even when cannula is bended
- with protective tube to avoid injuries by the needle
- the protective tube supports maintaining the sterility
- contamination protection by extended plastic attachment
- easy insertion of the cannula
- notch length 19 mm
- suitable for ultrasound biopsy
- 1:1 graduated, every 5 cm a thicker line

Kanülen-Abweichung bei heute verfügbaren Biopsie-Kanülen mit Schrägschliff
Deviation of cannula when using conventional beveled needles



Gezieltere Gewebeprobe durch geringere Abweichung bei 3-kantigem Trokarschliff
More precise tissue sampling due to less deviation based on use of triangular trocar shaped needles



Ideallinie zum Zielareal des Prostatagewebes
Optimal line for sampling of prostate tissue exactly in the target area

Farbkodierungen der Biopsie-Kanülen
Colour coding of the cannulas

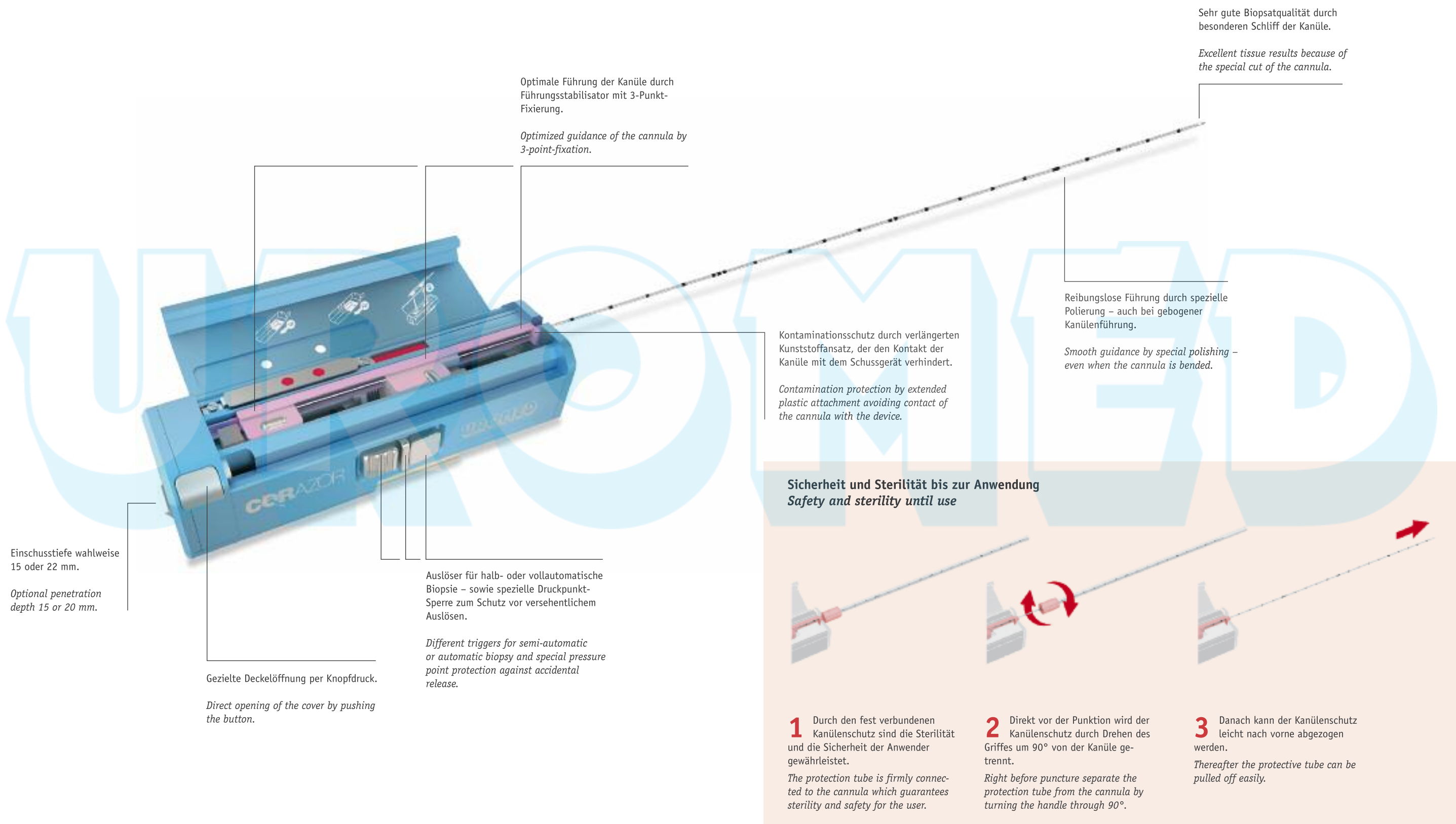
Table with 3 columns: Farbe/Colour, Gauge, Millimeter/Millimeters. Rows for gauges 16, 18, and 20.

Table with 4 columns: REF, Durchmesser/Diameter, Länge/Length, PZN/PZN. Rows for various cannula models and their specifications.

Table with 4 columns: REF, Durchmesser/Diameter, Länge/Length, PZN/PZN. Rows for CORAZOR 3K cannula models and their specifications.

CORAZOR[®] UROMED BIOPSIE-SYSTEM – zielgerichtet, punktgenau und sicher.

UROMED BIOPSY SYSTEM – precise, accurate and safe.





UROMED BIOPSIE SCHUSSGERÄT

REF 6020 / 6060

Die Innovation in punktgenauer Biopsie.

**UROMED Biopsy Device –
The Innovation in accurate
biopsy.**

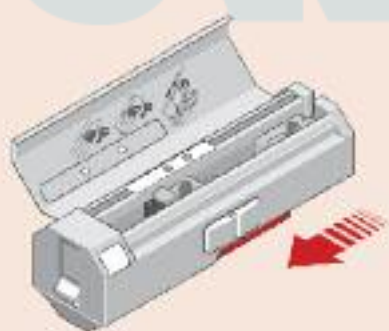
Zur Biopsie und Entnahme von
Weichgewebe

- hohe Federspannung für kraftvolles Eindringen und optimale Gewebeausbeute
- Auslöser für Halb- oder Voll-Automatik
- aufwendige Entsicherung entfällt durch spezielle Druckpunkt-Sperre
- hervorragend einhändig bedienbar
- leichtes Spannen
- leise in der Anwendung
- Deckelöffnung per Knopfdruck
- Einschusstiefe wahlweise 15 oder 22 mm
- Anzeige des Spannstatus
- maßgeschneiderter Einsatz mit »CORAZOR®« Stanzbiopsie-Kanülen

**For biopsy and soft tissue
sampling**

- *high spring tension for powerful puncture and optimized tissue samples*
- *triggers for automatic or semi-automatic sampling*
- *time extensive release is not necessary due to special pressure point protection*
- *excellent one-handed use*
- *easy cocking*
- *quiet application*
- *opening of the cover by pushing the button*
- *optional penetration depth 15 or 22mm*
- *status of the device is shown on the cocking indicator*
- *customised application with »CORAZOR®« Puncture Biopsy Cannulas*

Passgenaues Einlegen, sichere Handhabung, beste Ergebnisse.
Precise insertion, safe handling, best results.



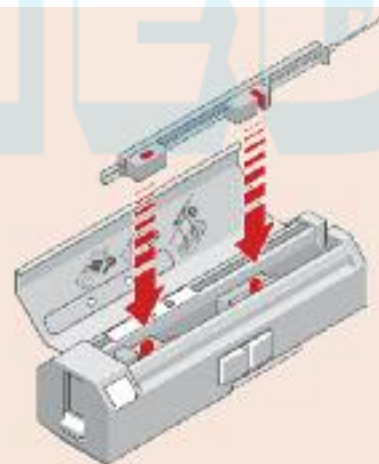
1 Vor (!) dem Einsetzen der Kanüle wird das Punktionsgerät **zweimal** bis zum Anschlag gespannt.

*Before (!) inserting the cannula the biopsy device has to be cocked **twice** up to the limit.*



2 Nach dem zweiten Spannen ist das Gerät bereit zur Aufnahme der Kanüle.

After the second cocking the device is ready to insert the cannula.



3 Kanüle einlegen und den Deckel schließen. Ein Entsichern ist nicht nötig – die Punktion kann mit einer Hand durchgeführt werden.

Insert cannula and close the cover. Safety release is not necessary – the puncture can be carried out with one hand.

REF REF	anwendbar mit »CORAZOR®«-Stanzbiopsie-Kanülen usable with »CORAZOR®« puncture cannulas
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6020.00 / 6060.00	Größen siehe vorherige Seiten for sizes please turn back
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Verpackung: unsteril
Verpackungseinheit: 1 Stück
Original-Karton: 1 Stück

Packing: unsterile
Packing unit: 1 piece
Original carton: 1 piece