

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)

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.: 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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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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MEDCERT Identification Number: 0482



Benannt durch/Designated by
Zentralsstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

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)

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Form F10010014e EN / Rev. 9 / 2019.11.14



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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 –

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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 –

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MEDCERT Identification Number: 0482



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
22113 Oststeinbek
Germany

has introduced, applies and maintains a quality management system in the area of activities, products/services and locations listed in the appendix.

The conformity of this quality management system to the requirements of the following standard has been verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date: 2022-06-28
Expiry date: 2024-03-12

Report No.: 1202IA28F
Procedure No.: QS – 1202
Certificate No.: 1202GB445220628

Hamburg, 2022-06-28

MEDCERT Certification Body
(Markus Bianchi)

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MEDCERT is a management systems certification body
accredited by DAkkS.

Appendix of certificate

Procedure No.: QS – 1202
Certificate No.: 1202GB445220628

Activities and products/services in the scope of certification

Design and development, manufacture, final inspection, and distribution of

- Medical devices for
 - Urology
 - Gynecology
 - Radiology

Locations in the scope of certification

UROMED Kurt Drews KG
Meessen 7
22113 Oststeinbek
Germany

UROMED Kurt Drews KG
Meessen 9
22113 Oststeinbek
Germany

UROMED Kurt Drews KG
Meessen 11
22113 Oststeinbek
Germany

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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

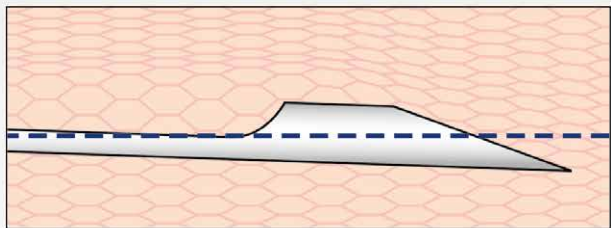
Zur Biopsie und Entnahme von
Weichgewebe

- 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

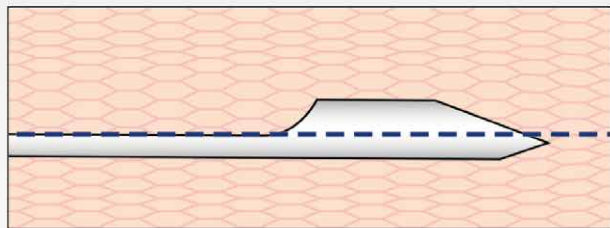
For biopsy and soft tissue
sampling

- 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 Abwei-
chung 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

Farbe Colour	Gauge Gauge	Millimeter Millimeters
	16	1,65
	18	1,20
	20	0,90

REF REF	Durchmesser Diameter	Länge Length	PZN PZN
6029.20	20 G / 0,90 mm	200 mm	10397949
6030.16	18 G / 1,20 mm	160 mm	10267632
6030.20	18 G / 1,20 mm	200 mm	10267649
6030.24	18 G / 1,20 mm	240 mm	10267655
6030.30	18 G / 1,20 mm	300 mm	10267572
6031.16	16 G / 1,65 mm	160 mm	10267589
6031.20	16 G / 1,65 mm	200 mm	10267595

REF REF	Durchmesser Diameter	Länge Length	PZN PZN
6025.20	18 G / 1,20 mm	200 mm	10391697
6025.24	18 G / 1,20 mm	240 mm	10267603

Verpackung: steril
Verpackungseinheit: 10 Stück
Originalkarton: 120 Stück

Packaging: sterile
Packaging unit: 10 pieces
Original carton: 120 pieces

Verpackung: steril
Verpackungseinheit: 10 Stück
Originalkarton: 120 Stück

Packaging: sterile
Packaging unit: 10 pieces
Original carton: 120 pieces