

# 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](mailto:info@medcert.de).

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
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.  
The certificate is only valid when provided entirely with all of its pages.  
To verify the validity of this certificate, contact [info@medcert.de](mailto:info@medcert.de).

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 –

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](mailto:info@medcert.de).

MEDCERT Identification Number: 0482



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

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

MEDCERT Identification Number: 0482

Form F10010014e EN / Rev. 9 / 2019.11.14



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
ZLG-BS-237.10.15

**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](mailto:info@medcert.de).

MEDCERT Identification Number: 0482



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
ZLG-BS-237.10.15

**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.  
The certificate is only valid when provided entirely with all of its pages.  
To verify the validity of this certificate, contact [info@medcert.de](mailto:info@medcert.de).

MEDCERT Identification Number: 0482



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
ZLG-BS-237.10.15



# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.  
1202GB445230925

Final assessment report no.  
1202AU28F

Effective date  
2023-09-25

Expiry date  
2024-03-12

This is to certify that

**UROMED Kurt Drews KG**

Meessen 7/11, 22113 Oststeinbek, Germany

Has introduced, applies, and maintains a management system at the sites listed on the following pages.

This management system has been audited and found to conform to the quality management systems standard

**EN ISO 13485:2016**

This certificate is valid for the scope of activities and products/services indicated on the following pages.

Place and date  
Hamburg, 2023-09-25



**DAkkS**

Deutsche  
Akkreditierungsstelle  
D-ZM-19630-04-00

For the issuing office  
DNV MEDCERT GmbH  
Pilatuspool 2, 20355 Hamburg, Germany



Lorenz Runge  
Director Certification Body

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact Medcert-Info@dnv.com

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

ACCREDITED UNIT: MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH (currently registered as DNV MEDCERT GmbH)  
Pilatuspool 2, 20355 Hamburg, Germany, Tel +49 40 2263325-0, www.med-cert.com, www.dnv.com

820115 EN Rev 1 2022.10.17

Certificate no.: [1202GB445230925](#)  
Place and date: [Hamburg, 2023-09-25](#)

### Sites covered by this certificate

UROMED Kurt Drews KG, Meessen 7/11, 22113 Oststeinbek, Germany

UROMED Kurt Drews KG, Meessen 9, 22113 Oststeinbek, Germany

UROMED Kurt Drews KG, Meessen 11, 22113 Oststeinbek, Germany

### Activities and products/services covered by this certificate

Design and development, manufacture, final inspection and distribution of

- Medical devices for
  - Urology
  - Gynecology
  - Radiology





# 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)

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

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

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](mailto:info@medcert.de).

MEDCERT is a management systems certification body  
accredited by DAkkS.