MED CERT®

Certification. Medical Only.

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)

Digitally signed by Dubalari Pavel
Date: 2022.10.06 11:50:50 EEST
Reason: MoldSign Signature
Location: Moldova

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MEDCERT is a DAkkS accredited management systems certification body

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-19630-04-00

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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 –

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MEDCERT is a DAkkS accredited management systems certification body

DAkkS Deutsche Akkreditierungsstelle D-ZM-19630-04-00

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

MEDCERT Identification Number: 0482

MED CERT®

Certification. Medical Only.

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

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

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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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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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MEDCERT Identification Number: 0482

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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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