

# 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

### **Urotech GmbH**

Medi-Globe Straße 1-5, 83101 Rohrdorf/Achenmühle, Germany

applies a quality assurance system for the medical devices listed in the annex according to the directive 93/42/EEC annex II. The approval is based on the result of the re-certification audit report no. 51450-Z1-01, the decision dated 2016-03-17 is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2016-04-01 to 2019-03-31

Certificate registration No.: 51450-16-00



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**

DEKRA Certification GmbH Stuttgart; 2016-03-17  
Notified Body ID-number: 0124

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

# Annex to the EC Certificate 51450-16-00 dated 2016-03-17

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## 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.

- MD 0101
  - Urinary bags
  - Dilation catheters
  - Accessories
    - Catheter syringes
    - Clamps
    - Feeding and drainage set
    - Connectors, adapter, Luer Lock
- MD 0106
  - Ureteral catheters/ occlusion catheters
  - Stone baskets
  - Ureteral access sheath

### Class II a:

- MD 0101
  - Ureteral catheters and sets
  - Transurethral catheters
  - Nephrostomy catheters and sets
- MD 0102
  - Cannulas
    - Puncture cannulas
    - Biopsy needles
- MD 0106
  - Guide wires
  - Dilators
  - Pusher
  - Urodynamics
    - Rectal pressure catheters
    - Measurement catheters

### Class II b:

- MD 0101
  - Nephrostomy catheters and sets
  - Suprapubic catheters and sets
  - Transurethral catheters
- MD 0203
  - Ureteral stents and sets