

# 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

**Certified location:**

Medi-Globe-Straße 1-5, 83101 Rohrdorf/Achenmühle, 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. 51450-Z2-00, the decision dated 2019-03-15 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-04-01 to 2024-03-31

Registration No.: 51450-16-01



Ruth Delbeck-Bayer  
DEKRA Certification GmbH Stuttgart; 2019-03-15  
Notified Body ID-number: 0124



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**

# Annex to the EC Certificate No. 51450-16-01

Valid from 2019-04-01 to 2024-03-31

Revision status of the annex: 0 dated 2019-03-15

Devices/device categories included in the certificate:

## Class I s:

- Urinary Bags
- Dilation Catheters
- Accessoires
  - Catheter Syringes
  - Clamps
  - Feeding and Drainage Set
  - Connectors, Adapter, Luer Lock
- Ureteral Catheters / Occlusion Catheters
- Stone Baskets
- Ureteral Access Sheath

## Class IIa:

- Ureteral Catheters and Sets
- Transurethral Catheters and Sets
- Nephrostomy Catheters and Sets
- Cannulas
  - Puncture Cannulas
  - Injection Cannulas
  - Biopsy Needles
- Guide Wires
- Dilators and Sets
- Pusher
- Urodynamics

## Class IIb:

- Nephrostomy Catheters and Sets
- Suprapubic Catheters and Sets
- Transurethral Catheters
- Ureteral Stents and Sets



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