

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



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

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
ZLG-BS-295.10.02
www.zlg.de

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



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

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de