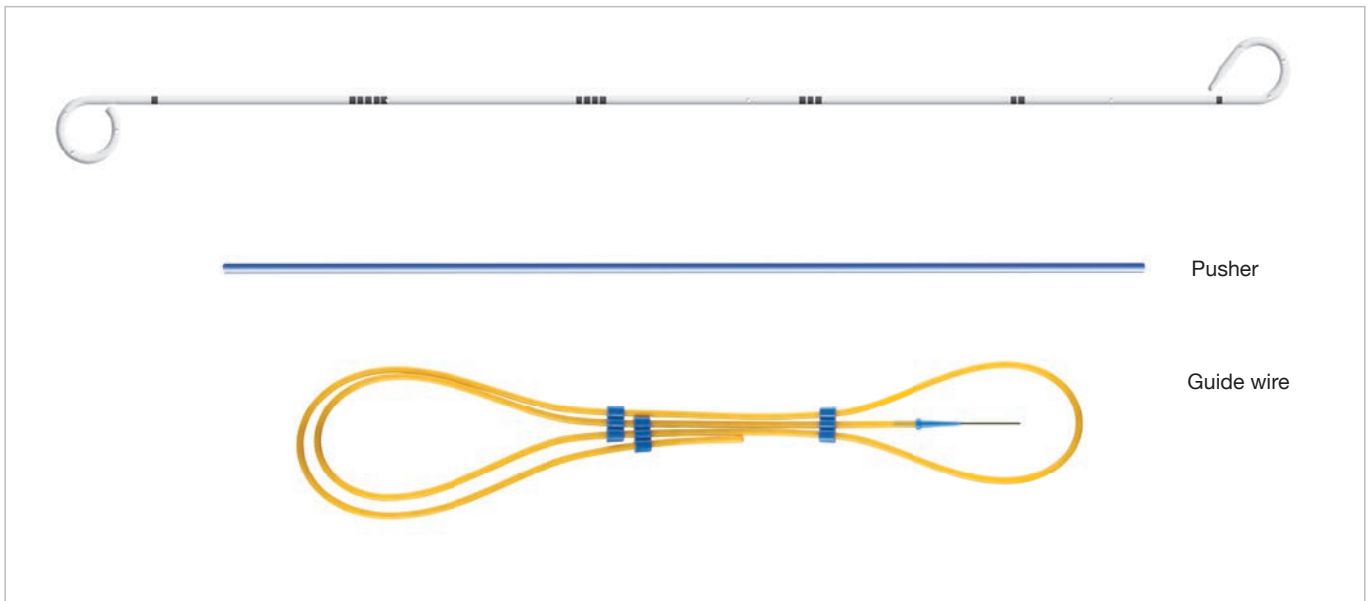


URETERAL STENTS

VISIOSTAR STANDARD Double-J Ureteral Stent Set

DESCRIPTION



Ureteral Stent

- ◆ Polyurethane
- ◆ Drainage openings in pigtails and shaft
- ◆ Open or closed tip
- ◆ Markings for exact positioning
- ◆ Radiopaque

Pusher

- ◆ Length: 40 cm

Guide wire

- ◆ PTFE coating

Clip

- ◆ In sets with closed tip



URETERAL STENTS

VISIOSTAR STANDARD Double-J Ureteral Stent Set

| Open tip | | | | | | | |
|------------------------------|---------------------------------|--------------|-------------|--------------------|------------------|----------|----------------|
| Order number with Guide wire | Order number without Guide wire | Size (CH/FR) | Length (cm) | Wire ϕ (inch) | Wire length (cm) | Wire tip | Wire stiffness |
| ST-194722 | ST-1954722 | 4.7 | 22 | 0.028" | 150 | straight | standard |
| ST-194724 | ST-1954724 | 4.7 | 24 | 0.028" | 150 | straight | standard |
| ST-194726 | ST-1954726 | 4.7 | 26 | 0.028" | 150 | straight | standard |
| ST-194728 | ST-1954728 | 4.7 | 28 | 0.028" | 150 | straight | standard |
| ST-194730 | ST-1954730 | 4.7 | 30 | 0.028" | 150 | straight | standard |
| ST-190624 | ST-195624 | 6 | 24 | 0.035" | 150 | straight | standard |
| ST-190626 | ST-195626 | 6 | 26 | 0.035" | 150 | straight | standard |
| ST-190628 | ST-195628 | 6 | 28 | 0.035" | 150 | straight | standard |
| ST-190630 | ST-195630 | 6 | 30 | 0.035" | 150 | straight | standard |
| ST-190724 | ST-195724 | 7 | 24 | 0.035" | 150 | straight | standard |
| ST-190726 | ST-195726 | 7 | 26 | 0.035" | 150 | straight | standard |
| ST-190728 | ST-195728 | 7 | 28 | 0.035" | 150 | straight | standard |
| ST-190730 | ST-195730 | 7 | 30 | 0.035" | 150 | straight | standard |
| ST-190824 | ST-195824 | 8 | 24 | 0.038" | 150 | straight | standard |
| ST-190826 | ST-195826 | 8 | 26 | 0.038" | 150 | straight | standard |
| ST-190828 | ST-195828 | 8 | 28 | 0.038" | 150 | straight | standard |
| ST-190830 | ST-195830 | 8 | 30 | 0.038" | 150 | straight | standard |
| ST-190924 | ST-195924 | 9 | 24 | 0.038" | 150 | straight | standard |
| ST-190926 | ST-195926 | 9 | 26 | 0.038" | 150 | straight | standard |
| ST-190928 | ST-195928 | 9 | 28 | 0.038" | 150 | straight | standard |
| ST-190930 | ST-195930 | 9 | 30 | 0.038" | 150 | straight | standard |
| ST-191024 | ST-1951024 | 10 | 24 | 0.045" | 150 | straight | standard |
| ST-191026 | ST-1951026 | 10 | 26 | 0.045" | 150 | straight | standard |
| ST-191028 | ST-1951028 | 10 | 28 | 0.045" | 150 | straight | standard |
| ST-191030 | ST-191030 | 10 | 30 | 0.045" | 150 | straight | standard |

Variants with sutures on the bladder end are available on request.

STONE BASKETS

VISIOCATCH STONE BASKETS

Super-elastic Nitinol core enclosed in a highly elastic polyamide tube*

"TIPLESS"



- ◆ Nitinol core enclosed
- ◆ Flexible tip for good maneuverability in the renal pelvis region
- ◆ High tensile strength, and good pressure and torque stability resulting from lasered baskets
- ◆ Handle can be disconnected and reconnected
- ◆ Optimal kink-resistance due to metal-reinforced inner tube
- ◆ Ergonomic scissor grip for easy handling
- ◆ The basket for the greatest demands

| Order number | Size (CH/FR) | Wires | Operating length (cm) | Basket length (mm) | Basket diameter (mm) |
|--------------|--------------|-------|-----------------------|--------------------|----------------------|
| DO-99194120 | 1.9 | 4 | 120 | 15 | 11 |

VISIOCATCH STONE BASKETS

Super-elastic Nitinol

"HELICAL"



| Order number | Size (CH/FR) | Wires | Operating length (cm) | Basket length (mm) | Basket diameter (mm) | Tip length (mm) |
|--------------|--------------|-------|-----------------------|--------------------|----------------------|-----------------|
| DO-903475 | 3.0 | 4 | 90 | 40 | 12 | 3 |
| DO-9034120 | 3.0 | 4 | 120 | 40 | 12 | 3 |

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

A handwritten signature in black ink, appearing to read 'Ruth Delbeck-Bayer', written over a horizontal line.



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
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





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

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
**uroVision Gesellschaft für medizinischen
Technologie-Transfer mbH**

Pullacher Straße 4, 83043 Bad Aibling, Germany

Certified locations:

Pullacher Straße 4, 83043 Bad Aibling, 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. 50658-Z5-00, the decision dated 2019-01-25 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-01-26 to 2024-01-25

Registration No.: 50658-16-04



Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-01-25
Notified Body ID-number: 0124



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. 50658-16-04

Valid from 2019-01-26 to 2024-01-25

Revision status of the annex: 0 dated 2019-01-26

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.

- Urinary Bags
- Transurethral Catheter
- Accessories:
 - Catheter syringes
 - Clamps
 - Connectors, adapter, Luer Lock
- Ureteral Catheter
- Stone Basket

Class II a:

- Ureteral Catheters and Sets
- Transurethral Catheters
- Nephrostomy Catheter and Sets
- Cannulas:
 - puncture cannulas
 - biopsy needles
- Guide Wires
- Dilators
- Pusher
- Urodynamics:
 - Rectal pressure catheters
 - Measurement catheters

Class II b:

- Nephrostomy Catheter and Sets
- Suprapubic Catheter and Sets
- Transurethral Catheter and Sets
- Ureteral Stent and Sets





Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2019-01-25
Notified Body ID-number: 0124

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

CERTIFICATE



EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the company

Urotech GmbH

Scope of certification:

Design, development, manufacturing and distribution as well as contract manufacturing/contract servicing of medical devices for urology and endourology¹

Storage and distribution of medical devices for urology and endourology²

Certified location:

Medi-Globe-Straße 1-5, 83101 Rohrdorf/Achenmühle, Germany¹

Südring 21, 46342 Velen-Ramsdorf, Germany²

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 51450-Z2-00.

This certificate is valid from 2019-04-01 to 2022-03-31

Registration No.: 51450-14-00


Ruth Delbeck-Bayer



DEKRA Certification GmbH Stuttgart; 2019-03-15



Deutsche
Akkreditierungsstelle
D-ZM-16029-08-00