

# 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*



**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](http://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](http://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



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