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

DEKRA Certification GmbH • Stuttgart, Handwerkstraße 15 • D-70565 DEKRA Certification

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
www.zlg.de
ZLG-BS-295.10.02

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
  - Measurment catheters

Class II b:

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

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