CERTIFICATE

Number: 2187895

DEKRA

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Urotech GmbH

Medi-Globe Straße 1-5 83101 Rohrdorf/Achenmühle Germany

including the implementation meets the requirements of the standard:

ISO 13485:2003

Scope:

Design and Development, Production and Distribution of Foley Catheters, Guide Wires, Ureterale Stents and Sets with and without Phosphorycholine Coating, Ureteral Catheters, Nephrostomy Catheters and Sets, Suprapubic Catheters and Sets, Stone Extraction Baskets, Urodynamic Catheters, Dilators, Puncture Needles, Pushers and Accessories for Urology and Endourology.

Certificate expiry date:	1 March 2019
Certificate effective date;	
Certified since:	31 March 2016

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.

drs. G.J. Zoetbrood Managing Director ing. A.A.M. Laan Certification Manager

DEKRA Certification B.V. is a CMDCAS recognized registrar. © Integral publication of this certificate and adjoining reports is allowed



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ADDENDUM

To certificate: 2187895

The management system of the organization(s) and/or location(s) of:

Urotech GmbH

Medi-Globe Straße 1-5 83101 Rohrdorf/Achenmühle Germany

Certified additional organization(s) and/or locations: Organization/Location Different scope

Urotech GmbH Südring 21 46342 Velen Germany Central store with incoming testing, commissioning goods, pre-shipment inspection and shipping.

Addendum expiry date: Addendum effective date: 1 March 2019 31 March 2016

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396