ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 15 05 46982 015

Manufacturer:

Urotech GmbH
Medi-Globe-Str. 1-5
83101 Achenmühle
GERMANY

Facility(ies):

Urotech GmbH
Medi-Globe-Str. 1-5, 83101 Achenmühle, GERMANY

Product Category(ies):

Ureteric Stents and Nephrostomy Catheters and -Sets with Phosphorylcholine coating
Ureteric Stents and -Sets of Tecoflex Material
Suprapubic Catheters and -Sets
Nephrostomy Catheters and -Sets
Guidewires
Foley Catheters

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713061066

Valid from: 2015-08-13
Valid until: 2020-06-02

Date, 2015-08-14

Hans-Heiner Junker

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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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