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

Product Service

EC-CERTIFICATE

Full Quality Assurance System

(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)

No. G1 10 05 46982 007

Manufacturer:

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

Facility(ies):

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

Product Category(ies):

Ureteric Stent Sets and Nephrostomy-Catheter-Sets with Phosphorylcholine coating, Ureteric Stents and -Sets of Tecoflex Material, Suprapubic Catheters and -Sets, Nephrostomy Catheters and -Sets, Guidewires and 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 products / product categories according to Annex II section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class III products an additional Annex II.4 certificate is mandatory. See also notes overleaf.

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Hans-Heiner Junker

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TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

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