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

Product Service

EC-CERTIFICATE

Production Quality Assurance System

(Annex V of the Directive 93/42/EEC on Medical Devices)

No. G2S 10 08 46982 009

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):

Ureter-Dilation-Sets, Ureteral-Catheters as well as Adapters and Introducers, Urodynamic-Sets, Urodynamic Catheters, Rectal Catheters, Retrieval Baskets - Urological Stone and Urine Bags

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture according to Annex V, section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective product / product categories and conforms to the provisions of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: 71373756

Valid until: 2015-08-03

Date, 2010-08-04

Hans-Heiner Junker

447002

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

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®