EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1957139-1

Manufacturer: BS Medical Tech Industry SAS
2 rue de l'Avenir
67470 Niederroedern
France

Products: Single use disposable products and equipment for urology and enteral nutrition:
- Ureteral Catheters
- Ureteral Stents
- Ureteral Access Sheath
- Ureteral Occlusion Catheter
- Nephrostomy Sets
- Percutaneous Gastrostomy Sets
- Dilator (nephrostomy single component)

For the following devices the scope covers only the aspects of the manufacture concerned with the securing and maintaining sterile conditions:
- Adapter MLL / Spout (nephrostomy single component)
- Ureteral Catheter-Adapter
- Ureteral Stent-Adapter

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

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TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierstelle

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.