Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System Directive 93/42/EEC on Medical Devices (MDD), Annex V (Devices in Class IIa, IIb or III)

No. G2 003920 0003 Rev. 00

Manufacturer: **Betatex S.p.a.**
Viale Europa Zona Industriale
06083 Ospedalicchio Bastia Umbra (PG)
ITALY

Facility(ies): Betatex S.p.a.
Viale Europa Zona Industriale, 06083 Ospedalicchio Bastia Umbra (PG), ITALY

ProductCategory(ies): **Disposable surgical kits for Orthopaedic, Ophthalmic, Urology, Gynaecology, Cardiology, Neurology, General surgical operation. Surgical loops arteries (red) veins (blue) nerves and tendons (white) ureters. Disposable sterile singular devices: Nonwoven Gauze, Cotton Gauze, Syringe, Needles, Manifolds, Stopcocks, Extension Lines, Infusion Line**

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

Report No.: ITA1073637

Valid from: 2018-09-27
Valid until: 2023-09-26

Date, 2018-09-05

Stefan Preiß

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD
A4 / 07.17