ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

TÜV SÜD 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 026513 0027 Rev. 01

Manufacturer:

TIK d.o.o. Proizvodnja medicinskih pripomockov
Goriska cesta 5b
5222 Kobarid
SLOVENIA

Facility(ies):

TIK d.o.o. Proizvodnja medicinskih pripomockov
Goriska cesta 5b, 5222 Kobarid, SLOVENIA

Product Category(ies):

Sterile Disposables for Anesthesia, Emergency and Intensive Care (class IIa)
Sterile Disposables for Injection, Infusion, Transfusion and Dialysis (class IIa)
Sterile Disposables for In-Vitro Fertilization (IVF) and Assisted Reproduction Technologies (ART) (class IIa)

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.: 713175638

Valid from: 2020-02-12
Valid until: 2024-05-26

Date, 2020-02-12

Christoph Dicks
Head of Certification/Notified Body

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

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

TÜV®

A4 / 07.17