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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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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 I in sterile conditions, sterilised systems or procedure packs)

No. G2S 026513 0028 Rev. 00

Manufacturer

**TIK d.o.o. Proizvodnja
medicinskih pripomočkov**

Goriska cesta 5b
5222 Kobarid
SLOVENIA

Product Category(ies):

**Sterile Disposables for Anesthesia,
Emergency and Intensive Care
(Class I Sterile)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G2S 026513 0028 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G2S_026513_0028_Rev._00)

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Valid from: 2020-10-05

Valid until: 2024-05-26

Date, 2020-10-05

Christoph Dicks
Head of Certification/Notified Body