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

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 17 03 26513 025

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 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. See also notes overleaf.

Report No.: 713101764_1

Valid from: 2017-04-22
Valid until: 2022-04-21

Date, 2017-04-03

Stefan Preiß

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

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