[redacted]

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 025197 0016 Rev. 00

Manufacturer	**Sengewald Klinikprodukte GmbH** Adlerstr. 2 83101 Rohrdorf / Thansau GERMANY
Product Category(ies):	**Disposable OR-Drape Systems, Protective Products for Patient Protection, OR Apparel, Custom Procedure Trays acc. to Article 12 of Directive 93/42/EEC, Urine Drainage Systems and Accessories**

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.: 713174666

Valid from: 2020-03-02
Valid until: 2024-05-26

Date, 2020-03-02

[redacted]

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