



Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzntechnik und
 Medizinprodukten
 www.zglg.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 I in sterile conditions, sterilised systems or procedure packs)

No. G2S 068194 0008 Rev. 00

Manufacturer **Zhangjiagang Zhiyi Medical Health Products Co., Ltd.**

Renmin Road, Leyu Town
 215622 Zhangjiagang City, Jiangsu Province
 PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies): **Surgical Drape, Surgical Gown, Sterile Surgical Kit, Face Mask.**

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.: SH18524EXT01

Valid from: 2019-01-23

Valid until: 2024-01-22

Date, 2018-11-29

Stefan Preiß