



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.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.:

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2024-01-22

Date,

2018-11-29

Stefan Preiß



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