



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 052464 0014 Rev. 00

Manufacturer

Topwide (Hubei) Medical Products Manufacturer

19# Xianhong Road, Xinlirenkou, Zhanggou Town
433012 Xiantao City, Hubei Province
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

**Sterile Lap Sponges without X-Ray,
Sterile Gauze Sponges (Balls) without X-Ray,
Sterile Non-Woven Sponges (Balls) without X-Ray,
Basic Dressings Pack without X-Ray,
Sterile Bandage,
Surgical Gown, Drapes**

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.:

SH18173EXT01

Valid from:

2019-03-11

Valid until:

2024-03-10

Date,

2019-01-02

Stefan Preiß



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