



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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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 095972 0004 Rev. 01

Manufacturer

Zhende Medical Co., Ltd.

Gaobu Town
312035 Shaoxing, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Zhende Medical Co., Ltd.
Gaobu Town, 312035 Shaoxing, Zhejiang, PEOPLE'S REPUBLIC
OF CHINA

Product Category(ies):

**Sterile Non-woven without X-ray Thread,
Sterile Gauze Swabs without X-ray Thread,
Sterile Drapes, First Aid Kit,
Sterile Bandage, Sterile Absorbent Pad,
Sterile Cohesive Bandage
Sterile Surgical Gown,
Sterile Adhesive Surgical Dressing**

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.

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Valid from: 2019-08-05

Valid until: 2024-05-26

Date, 2019-08-05

Stefan Preiß
Head of Certification/Notified Body