



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 095972 0003 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):

Lap Sponges,
Procedural Dressing Trays,
Sterile Gauze Swabs with X-ray Thread,
Sterile Non-woven Swabs with X-ray Thread,
Sterile Paraffin Dressing,
Super Absorbent Dressing,
Silicone Foam Dressing,
Foam Dressing

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

SH19071EXT02

Valid from:

2019-08-05

Valid until:

2024-05-26

Date,

2019-08-05

Stefan Preiß
Head of Certification/Notified Body