



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 081989 0007 Rev. 02

Manufacturer:

Changzhou Waston

Medical Appliance Co., Ltd.

No. 9 Xihu Road, Wujin Hi-Tech Industry Zone

213164 Changzhou, Jiangsu

PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)

Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies):

**General Spinal System, Metallic Bone Plates,
Metallic Bone Screws, Metallic Intramedullary Nails,
Circular Staplers, Linear Staplers, PPH Staplers,
Linear Cutters, Curved Cutters, Orthopaedic
External Fixation System, Endoscopic Cutters,
Negative Pressure Wound Therapy System,
Disposable Trocar, Sternal Fixation System,
Intervertebral Fusion Cage, Kyphoplasty Balloon
Catheter, Kyphoplasty Tool Kit**

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.:

SH1868707

Valid from:

2019-04-02

Valid until:

2023-03-07

Date,

2019-04-02

Stefan Preiß

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Facility(ies):

Changzhou Waston Medical Appliance Co., Ltd.

No. 9 Xihu Road, Wujin Hi-Tech Industry Zone, 213164

Changzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

Changzhou Waston Medical Appliance Co., Ltd.

Nanxiashu Street, Wujin Zone, No. 5 Longxiang Road, 213164

Changzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA