



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 16 01 81989 005

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**

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.:

SH1568704

Valid from:

2016-02-25

Valid until:

2018-03-07

Date, 2016-02-24

Stefan Preiß



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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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 16 01 81989 005**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



Product Service

CERTIFICATE

No. Q1N 16 01 81989 006

Holder of Certificate: **Changzhou Waston Medical Appliance Co., Ltd.**

No.9 Xihu Road
Wujin Hi-Tech Industry Zone
213164 Changzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

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



Certification Mark:



Scope of Certificate:

**Design and Development,
Production and Distribution of
General Spinal System, Metallic Bone Plates,
Metallic Bone Screws, Curved Cutters,
Metallic Intramedullary Nails,
Circular Staplers, Linear Staplers,
PPH Staplers, Linear Cutters,
Orthopaedic External Fixation System,
Endoscopic Cutters**

**Applied
Standard(s):**

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

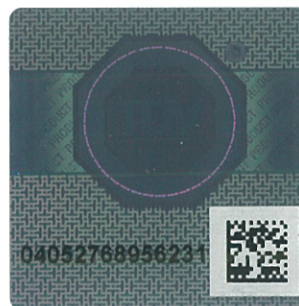
Report No.: SH1568704

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Valid until: 2019-03-07

Date, 2016-02-24

Stefan Preiß



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