



# Certificate

No. Q5 081989 0008 Rev. 01

**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

**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, Negative Pressure Wound Therapy System, Disposable Trocar, EHMS Endoscopic Hernia Multifeed Stapler, Sternal Fixation System, Intervertebral Fusion Cage, Kyphoplasty Balloon Catheter, Kyphoplasty Tool Kit, Balloon Inflator**

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.:** SH1868707

**Valid from:** 2019-04-02

**Valid until:** 2022-03-07

**Date,** 2019-04-02

Stefan Preiß

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**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

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|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Facility(ies):</b> | Changzhou Waston Medical Appliance Co., Ltd.<br>No. 9 Xihu Road, Wujin Hi-Tech Industry Zone, 213164<br>Changzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA       |
|                       | Changzhou Waston Medical Appliance Co., Ltd.<br>Nanxiashu Street, Wujin Zone, No. 5 Longxiang Road, 213164<br>Changzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA |