

## Disposable Endoscopic Cutter Stapler and Cartridge

# Endoscopic

- Used in the tissue transection, resection and anastomosis of endoscopic surgery, gynaecology, paediatric and chest surgery.



The joint head can swing 88° from left to right and rotate 360°.



The rotary knob of the joint rotates smoothly, steadily and non-sloshing.



A more convenient cartridge load-off button

- Better blood supply, better tissue thickness adaptability, less tissue crush injury
- Fixed anvil design: When anvil closed to the jaw, the anvil side stays still, the active side can pass through the narrow space easily, protect tissue and blood vessel.

### Stapler

Product Code	Model	Type	Basic Size ±10
12019101	HSD-S	Short	277
12019102	HSD-B	Standard	377
12019103	HSD-L	Extra-long	477

### Cartridge

Product Code	Model	Color	Suture Length ±5	Cutting Length ±5	Staple Height
12029302	HSZ-30-WT(R)	W White	30	25	2.0/2.5/3.0
12029303	HSZ-30-PT(R)	P Purple			3.0/3.5/4.0
12029453	HSZ-45-WT(R)	W White			2.0/2.5/3.0
12029454	HSZ-45-PT(R)	P Purple	45	40	3.0/3.5/4.0
12029455	HSZ-45-BT(R)	B Black			4.0/4.5/5.0
12029603	HSZ-60-WT(R)	W White			2.0/2.5/3.0
12029604	HSZ-60-PT(R)	P Purple	60	55	3.0/3.5/4.0
12029605	HSZ-60-BT(R)	B Black			4.0/4.5/5.0
12029645	HSZ-45-W(R)	W White			2.5
12029745	HSZ-45-B(R)	B Blue	45	40	3.5
12029545	HSZ-45-D(R)	D Gold			4.1
12029445	HSZ-45-G(R)	G Green			4.8
12029160	HSZ-60-W(R)	W White	60	55	2.5
12029760	HSZ-60-B(R)	B Blue			3.5
12029560	HSZ-60-D(R)	D Gold			4.1
12029460	HSZ-60-G(R)	G Green			4.8



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 18 01 81989 007

**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.:**

SH18687EXT01

**Valid from:**

2018-03-08

**Valid until:**

2023-03-07

Date, 2018-01-15

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 18 01 81989 007****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

# C E R T I F I C A T E

No. Q1N 16 01 81989 006

**Holder of Certificate:** **ChangzhouWaston  
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 TOV SOD 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

**Valid from:** 2018-03-08

**Valid until:** 2021-03-07

**Date,** 2018-02-24

*S. Preil*  
Stefan Preil



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Akkreditierungsstelle  
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