## FHD Series of Reusable Linear Stapler and Disposable Cartridge

## Linear

• Applied in the whole digestive tract for transection and resection of inernal tissue.





## 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:	<b>Changzhou Waston</b> <b>Medical Appliance Co., Ltd.</b> 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 N 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.		

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: Valid until: 2018-03-08 2023-03-07



Date, 2018-01-15

Stefan Preiß

I. In

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

Page 1 of 2





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

Page 2 of 2