

Good Manufacturing Practice for Medical Devices Pass Notice

Name of Manufacturer: Changzhou Waston Medical Appliance Co.,Ltd

Address of Manufacturer:

9 Xihu Road, Wujin Hi-Tech Industry Zone, Changzhou 213164, China.

Address of Manufacturing Site:

9 Xihu Road, Wujin Hi-Tech Industry Zone, Changzhou 213164, China.

99 Hehai Middle Road, Xinbei District, Changzhou 213000, China.

These provisions of Good Manufacturing Practice (GMP) for Medical Device (Experimental), in accordance with the State Food and Drug Administration Law of the People's Republic of China and the Regulations for Implementation of the State Food and Drug Administration Law of the People's Republic of China, are enacted to regulate the manufacturing and quality management of Medical Device.

Evaluation Results: Pass.

Name of Device:

See attachment.

Jiangsu State Food and Drug Administration
October, 20th, 2011

Good Manufacturing Practice Evaluation Summary Sheet

Name of Manufacturer:	Changzhou Waston Medical Appliance Co.,Ltd			
Address of Manufacturer:	9 Xihu Road, Wujin Hi-Tech Industry Zone, Changzhou 213164, China.			
Inspection Date:	October, 12th- 14th , 2011			
Classification of Product:	■Sterilized Product		■Implants	
Product Name:	Spinal System, Enlacement Steel Wire and Buckle, Metallic Bone Plates, Metallic Bone Screws, Metallic Intramedullary Nails, Rib Plates System, Anterior Cervical Plate System, LOC Plates System, WHY Series Disposable Circular Stapler, WHD Series Reusable Circular Stapler and Cartridge, FHY Series Disposable Linear Stapler, FHD Reusable Linear Stapler and Cartridge, GHY Series Disposable PPH Stapler, GHD Series Reusable PPH Stapler and Cartridge, QHY Series Disposable Linear Cutter, ZHY Series Auto Linear Stapler, HQY Series Disposable Curved Cutter Stapler and Cartridge, HFY Disposable Purse String Forceps, etc.			
Assessment Route:	The Good Manufacturing Practice for Implants (Experimental); The Good Manufacturing Practice for Sterilized Products (Experimental).			
Evaluation team:	Team	Name	Title	Organization
	Supervisor	Cheng Yu		Division of Manufacturing Supervision, Changzhou Branch.
	Deputy Supervisor	Wang Fang		Division of Manufacturing Supervision, Wujin Branch.
	Deputy Supervisor	Wang Yan Lin		Division of Manufacturing Supervision, Wujin Branch.
Responsible Personnel	Name	Title		Department
	Zhang Hua Quan	Engineer		
	Yang Jiang Ping	Engineer		Production (Orthopaedic)
	Zhou Hua			Quality Control (Orthopaedic)
	Wang Cai Ya			Quality Control (Surgical Stapler)
	Chen Jian Gang			Production (Surgical Stapler)
	Zhou Guo Xing	Engineer		Quality Control (Orthopaedic)
	Zhou Jin			Supply
	Zhou Feng Di			Sales
	Zhou Hai Yan			Administration
Wang Xiao Xian			Quality Control	