

Declaration of Conformity

Manufacturer:	Changzhou Waston Medical Appliance Co., Ltd. No.9 Xihu Road, Wujin Hi-Tech Industry Zone, 213164 Changzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA
Product Name	Surgical Instruments
Classification:	(MDD Annex IX): I, rule 5
Conformity Assessment Route: Annex II.3	

We herewith declare that the surgical instruments for transient use meet the transposition into national law, the provisions of the following EC Council Directives and Standards.

All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives :

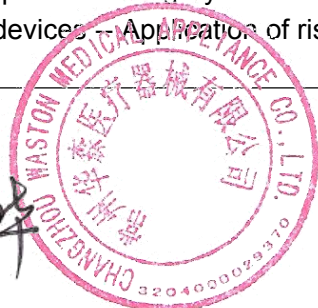
Medical Device Directive : COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

List of Applicable Standards:

- ISO 780:2015 Packaging -- Pictorial marking for handling of goods
- ISO 7153-1:1991,MOD Surgical instruments-Metallic material-Part 1:Stainless Steel
- ISO 5832-1:1997,MOD Implants for surgery-Metallic materials-Part 1:Wrought stainless Steel
- ISO 14971:2007 Medical devices -- Application of risk management to medical devices

Signature:





Name: Hua Zhou

Position: Management Representative

12 JULY 2018