

Declaration of Conformity

We

Changzhou Waston Medical Appliance Co,.Ltd,

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

declare our own responsibility that the products:

10180/Spinal System 11100/Cervical System 10200/Plate System 10250/Rib Plate System 10600/Intrameduallary Nails 10700/CLP(LCP) System

are in conformity with the following standards or other normative documents:

Directive 93/42/FEC

TÜV SÜD Product Service GmbH declares that we have implemented a quality assurance system for design, manufacture and final inspection of the respective devices/device categories in accordance with MDD Annes II

G1 13 01 81989 002

TÜV SÜD Product Service GmbH certifies that we have established and are maintaining a quality system which meets the requirements of ISO 13485:2003

ISO 13485:2003

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Place and Date of publication

Director of Marketing and Sales, Changzhou Waston Medical Appliance, Ltd

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Managing Director, Changzhou Waston Medical Appliance .. Ltd