ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Digitally signed by Bunic Gheorghe
Date: 2022.05.30 14:21:19 EEST
Reason: MoldSign Signature
Location: Moldova

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

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Date, 2018-01-15

Stefan Preiß

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

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Facility(ies):

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No.9 Xihu Road, Wujin Hi-Tech Industry Zone,
213164 Changzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

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