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Add value.
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TÜV SÜD Product Service GmbH · Ridlerstrasse 65 · 80339 Munich · Germany

Changzhou Waston
Medical Appliance Co., Ltd.
No. 9 Xihu Road, Wujin Hi-Tech Industry Zone
213164 CHANGZHOU, JIANGSU
PEOPLE'S REPUBLIC OF CHINA

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
81989	713293552			2023-08-08	1 of 5

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 081989 0011 Rev. 00

Reference: 713293552

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: CN-MF-000004851

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

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- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3a) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further copies, amendments and / or changes of the confirmation letter according to effort.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
08.08.2023

TÜV SÜD Product Service GmbH
Medical and Health Services

Ms. Yi Wu
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Arianit Fazlija
Application Reviewer

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Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 1 Metallic Bone Plates (Basic UDI -DI: 69365944UEP8Z 69365944UEPS3W 69365944LEP7L 69365944LEPSZU 69365944MPJP 69365944MPS8Y 69365944RPK6 69365944SFS8Y)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate # G1 081989 0007 Rev.03; NB# 0123
Device 2 Metallic Bone Screws (Basic UDI -DI: 69365944MBSKZD 69365944MBSKSZF 69365944MBSPZP 69365944MBSPSZW 69365944MBSSZV 69365944MBSSS2A)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate # G1 081989 0007 Rev.03; NB# 0123
Device 3 Metallic Intramedullary Nails (Basic UDI -DI: 69365944FNHW 69365944FNS7P 69365944HNJ4 69365944HNS7Z 69365944TNK8 69365944TNS9V)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate # G1 081989 0007 Rev.03; NB# 0123
Device 4 Disposable Endoscopic Cutter Stapler (Basic UDI -DI: 69365944ECS6H 69365944ECSRY8 69365944HSC7G 69365944HSD7J)	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate # G1 081989 0007 Rev.03; NB# 0123
Device 5 Cartridge for Disposable Endoscopic Cutter Stapler (Basic UDI -DI: 69365944ECZ6X	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 081989 0007 Rev.03; NB# 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
69365944HSZ8W 69365944HSZR45 69365944HSZT49 69365944HSZTR5E 69365944HSZQR55 69365944HSZTQR9N)	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 6 Circular Staplers (Basic UDI -DI: 69365944CSHX 69365944TCS8U)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate # G1 081989 0007 Rev.03; NB# 0123
Device 7 Hemorrhoid and Prolapse Staplers (Basic UDI -DI: 69365944PSK6 69365944TPSA3)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate # G1 081989 0007 Rev.03; NB# 0123
Device 8 Linear Cutters (Basic UDI -DI: 69365944QHS8U 69365944QZSAJ 69365944QHD7W 69365944QZD9L)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate # G1 081989 0007 Rev.03; NB# 0123
Device 9 EHMS Endoscopic Hernia Multifeed Stapler (Basic UDI -DI: 69365944EHMSYH)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate # G1 081989 0010 Rev.00; NB# 0123

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Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Not applicable	☒ N/A	☒ N/A	☒ N/A

Confirmation Letter Revision History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2023/08/08	713293552	Initial issue

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD 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 081989 0007 Rev. 02

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, Negative Pressure Wound Therapy System, Disposable Trocar, Sternal Fixation System, Intervertebral Fusion Cage, Kyphoplasty Balloon Catheter, Kyphoplasty Tool Kit

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.: SH1868707

Valid from: 2019-04-02
Valid until: 2023-03-07

Date, 2019-04-02

Stefan Preiß

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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 081989 0007 Rev. 02

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

Changzhou Waston Medical Appliance Co., Ltd.
Nanxiashu Street, Wujin Zone, No. 5 Longxiang Road, 213164
Changzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

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

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 081989 0008 Rev. 03

Holder of Certificate: **Changzhou Waston Medical Appliance Co., Ltd.**
No. 9 Xihu Road, Wujin Hi-Tech Industry Zone
213164 Changzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of General Spinal System, Metallic Bone Plates, Metallic Bone Screws, Curved Cutters, Metallic Intramedullary Nails, Circular Staplers, Linear Staplers, PPH Staplers, Linear Cutters, Orthopaedic External Fixation System, Endoscopic Cutters, Negative Pressure Wound Therapy System, Disposable Trocar, EHMS Endoscopic Hernia Multifeed Stapler, Sternal Fixation System, Intervertebral Fusion Cage, Kyphoplasty Balloon Catheter, Kyphoplasty Tool Kit, Balloon Inflator, Disposable Medical Face Mask**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 081989 0008 Rev. 03

Report No.: SH2268701

Valid from: 2022-08-25
Valid until: 2025-03-07

Date, 2022-08-25

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 081989 0008 Rev. 03

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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

Production and Distribution of
General Spinal System, Metallic Bone Plates, Metallic Bone Screws, Curved Cutters, Metallic Intramedullary Nails, Circular Staplers, Linear Staplers, PPH Staplers, Linear Cutters, Orthopaedic External Fixation System, Endoscopic Cutters, Negative Pressure Wound Therapy System, Disposable Trocar, EHMS Endoscopic Hernia Multifeed Stapler, Sternal Fixation System, Intervertebral Fusion Cage, Kyphoplasty Balloon Catheter, Kyphoplasty Tool Kit, Balloon Inflator, Disposable Medical Face Mask

Changzhou Waston Medical Appliance Co., Ltd.
Nanxiashu Street, Wujin Zone, No. 5 Longxiang Road, 213164
Changzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of
General Spinal System, Metallic Bone Plates, Metallic Bone Screws, Curved Cutters, Metallic Intramedullary Nails, Circular Staplers, Linear Staplers, PPH Staplers, Linear Cutters, Orthopaedic External Fixation System, Endoscopic Cutters, Negative Pressure Wound Therapy System, Disposable Trocar, EHMS Endoscopic Hernia Multifeed Stapler, Sternal Fixation System, Intervertebral Fusion Cage, Kyphoplasty Balloon Catheter, Kyphoplasty Tool Kit, Balloon Inflator, Disposable Medical Face Mask

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EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.:	HD 2057271-1
Manufacturer:	Zhejiang Geyi Medical Instrument Co., Ltd. No.1,2 Factory, No.5, Hutang Road, Xiaya Town, Jiande City, 311606 Zhejiang P.R. China
Products:	Disposable Cutting Surgical Staplers, Disposable Surgical Staplers, Disposable Hemorrhoidal Surgical Staplers, Disposable Trocars, Disposable Suction Irrigation Sets, Disposable Endoscopic Retrieval Bags, Disposable Curved Cutting Staplers, Disposable Circumcision Staplers, Disposable Veress Insufflation Needles

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.:	15056254 014
Effective date:	2021-05-17
Expiry date:	2022-12-13
Issue date:	2021-05-17

TÜV Rheinland LGA Products GmbH

Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.