MINISTÉRIO DA SAÚDE

AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA

CERTIFICADO DE BOAS PRÁTICAS DE FABRICAÇÃO E CONTROLE DE PRODUTOS PARA SAÚDE

Considerando o disposto na Lei n.º 9.782, de 26 de janeiro de 1999, o Decreto nº 3.029, de 16 de abril de 1999 e a publicação no Diário Oficial da União por meio da Resolução RE n° 2795 na data de ***30/08/2022*** *certifico que a empresa, a seguir descrita, cumpre com a legislação sanitária vigente, quanto às Boas Práticas de Fabricação de produtos para saúde exigidas pela autoridade sanitária brasileira, estando sujeita a inspeções periódicas.*

Empresa: GM dos Reis Indústria e Comércio Ltda CNPJ: 60.040.599/0001-19

Endereço: Av. Pierre Simon de Laplace nº 600 Lote 3, Q. F, Quarteirão 9677, Techno Park, Campinas - SP CEP: 13069-320

Autorização de Funcionamento: 1024770 Expediente: 0811062/22-8

Certificado de Boas Práticas de Fabricação de Produtos para Saúde.

Materiais de uso médico das classes III e IV.

Motivo: Subsidiado por relatório de inspeção, requisito necessário para decisão do ato.

Validade até: 30/08/2024

Documento assinado eletronicamente por **Ana Carolina Moreira Marino Araujo**, **Gerente-Geral de Inspeção e Fiscalização Sanitária**, em 30/08/2022, às 19:26, conforme horário oficial de Brasília, com fundamento no § 3º do art. 4º do Decreto nº 10.543, de 13 de novembro de 2020 http://www.planalto.gov.br/ccivil_03/_ato2019-2022/2020/decreto/D10543.htm.

A autenticidade deste documento pode ser conferida no site https://sei.anvisa.gov.br/autenticidade, informando o código verificador **2030601** e o código CRC **E2758C6D**.

Materialização às 11 h 15 do 01 SET. 2022, após verificação no seguinte endereço eletrônico: sei.anvisa.gov.br/sei/autenticidade

5º TABELIÃO DE NOTAS - CAMPINAS - SP
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CAMPINAS, 01 SET 2022
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Autentico a presente cópia reprográfica conforme original a mim apresentado, do que dou fé
Ezequias Ferreira Naiva, Escrevente Autorizado
VÁLIDO SOMENTE COM SELO DE AUTENTICIDADE.

CONSELHO NACIONAL DE JUSTIÇA

BRASIL

APOSTILLE

(Convention de La Haye de 5 octobre 1961)

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Este documento público (This public document / Le présent acte public)	
2. Foi assinado por: (Has been signed by / A été signé par)	Ezequias Ferreira Neiva
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4. Tem o selo / carimbo de: (Bears the seal / stamp of / Est revêtu du sceau / timbre de)	AU0188AH0757289
Certificado (Certified / Attesté)	
5. Em: (At / À): CAMPINAS	6. No dia: (The / Le): 02/09/2022
7. Por: (By / Par):	MARIA APARECIDA AGOSTINHO FIGUEIREDO
8. Nº: (Nº / Sous nº):	1649776-22
9. Selo / Carimbo: (Seal / Stamp / Sceau / Timbre)	10. Firma: (Signature) Assinatura Eletrônica / Electronic Signature / Signature Électronique

BRASIL APOSTILA APOSTILLE — CONVENÇÃO DE HAIA DE 1961 - CONVENTION DE LA HAYE DE 1961

Tipo de Documento: (Type of document / Type d'acte) Certificado - Boas Práticas de Fabricação e Controle de Produtos Para Saúde - Ministério da Saúde

Nome do titular: (Name of holder of document / Nom du titulaire) GM DOS REIS INDÚSTRIA E COMÉRCIO LTDA

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Apostil

A6704266

BRASIL APOSTILA APOSTILLE — CONVENÇÃO DE HAIA DE 1961 - CONVENTION DE LA HAYE DE 1961

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, 25th, 2017

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,24th-25th,2017			
Classification of product:	■ Sterilized Product ■ Implants ■ Surgical Instruments			
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, Surgical Instruments,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		Divisions 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 personel	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 Feng Di		Administration
	Wang Xiao Xian		Quality Control
Production inspection Facility environment	Manufacturing environment : ■ general production □purified production Cleaning grade: □class 300,000 ■class 100,000 □class 10,000 □class 1,000,000 partially Inspection environment: ■general inspection room ■Sterile inspection room ■positive room ■Microorganism limit room		
Severe defect items (0)			
General defect items	Item	Description	
	0502	The decomposition of quality target is unreasonable.	
	0504	The content of management review is too simple and incomplete.	
	0601	No relevant authority for management representative in the official appointment documents	
	0702	Manufacturing, technology, quality department supervisor's revaluation requirement is lack of pertinence.	
	1003	Sedimentated bacteria sampling site in the cleaning workshop REC-VT is not clear.	
	1703	No trend analysis of Initial contaminating bacteria	
	1805	No rules for the person with wound cannot touch the products	
	1902	There is contradiction for clothing configuration requirements in sterile and clean uniform regulations.	
	2706	External document list is not updated, while the distribution record of documents is incomplete.	
	3201	The content of metallic locking plates R&D planning output file is incomplete.	
	4203	The content of qualified supplier selection, evaluation, revaluation is incomplete	
	4204	The record of supplier evaluation and revaluation is not standardized.	
	4401	Non-conformance of the verification for the procurement material	
	5602	Inconformity of faucets in the cleaning area	
	6301	Non-conformance between the requirement and the record for the soaking time in the forging verification.	
	6304	No product inspection record in PQ confirmation stage of CNC machine software	
	7301	Incomplete of the in-process parameter in the	

		package verification			
	7902	The content of in-process inspection and experiment is not clear			
	8202	The content of retention sample management rules is incomplete.			
	8302	The data analysis record of product performance feedback is incomplete			
	9302	The original record of re-inspection for unqualified products is not clear			
	10101	The correction and prevention mechanism for customers' feedback is not suitable. The efficiency evaluation of the correction mechanism is not enough.			
	10002	The statistical analysis of customers' feedback is not enough.			
	10501	There is just rule for the implants' retraction and analysis, no practical work			
Non-suitable inspection items (26)	Clause no.	0703, 0805, 1501, 1502, 3304, 4501, *4502, *4503, 4601, *4602, *4603, 4701, *4702, *4801, *4901, 4902, 5702, 6804, 7401, *7402, 7501, 7601, 7701, 8701, 8702			
		See annex			
On-site inspection result statistics	Inspection item	Standard items	Non-suitable items	Defect items	Defect percentage
	Key items	38	11	0	0
	General items	266	17	24	9.6%
	Total items	304	26		8.6%
Inspection conclusion	Suggestion:	■Pass inspection □After review □Fail inspection			
Inspector's signature	Team member	Wang Fang, Wang Yanlin			
	Team leader	Cheng Yu			
Manufacturer confirmation	Agree	Signature of chairman (seal)			
Inspection date	2017. 10. 25				

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

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

CHANGZHOU WASTON MEDICAL APPLIANCE CO.,LTD.

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

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

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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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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

Jack Lu

CHANGZHOU WASTON MEDICAL APPLIANCE CO., LTD. 常州华森医疗器械有限公司 3204000029370

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