



Fiscal Year 2020

## NOTIFICATION OF FDA REGISTRATION

This notifies that:

**Rider Bull Bio-Technique (Zhongshan) Co.,Ltd**  
**Block A,No.7 Yongxin Street,Qunlian Village,Tanzhou Town,**  
**Zhongshan, Guangdong, CHINA 528467**

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through UCL-REG SERVICE INC.

**Owner/Operator Number: 10077647**

<b>Listing No.</b>	<b>Product Code:</b>	<b>Device Name:</b>
D417882	IWP	Radiographic protective Glove- Disposable medical examination gloves

*UCL-REG SERVICE INC. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. UCL-REG SERVICE INC. makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. UCL-REG SERVICE INC. assumes no liability to any person or entity in connection with the foregoing.*

*Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."*

*The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, UCL-REG SERVICE INC. is not affiliated with the U.S. Food and Drug Administration.*



UCL-REGSERVICE INC.  
602 ROCKWOOD ROAD,WILMINGTON,  
NEW CASTLE DE 19802 USA

For and on behalf of  
UCL-REG SERVICE INC.

Cert. No.: M201073  
Issued Date: 10 Sep. 2020  
Expiration Date: 31 December 2020



MEDRIGHT TECH INC  
13525 40TH RD STE 3F  
FLUSHING, NY 11354  
[info@medright-tech.com](mailto:info@medright-tech.com)

Our Ref: 211073  
RIDER BULL BIO-TECHNIQUE (ZHONGSHAN) CO.,LTD  
Block A,No.7 Yongxin Street,Qunlian Village,Tanzhou Town,  
Zhongshan, Guangdong, 528467, CHINA

January 13, 2021  
Dear Chen Gengdong

### FDA Registration Confirmation

Thank you for appointing MEDRIGHT TECH INC as your U.S. Agent, we hereby state that we accepts the appointment to be the U.S. Agent for your products, and we have completed the registration activation confirmation for the **FDA Establishment Registration and Device Listing** with the US Food & Drug Administration for the **Fiscal Year 2021** of

**RIDER BULL BIO-TECHNIQUE (ZHONGSHAN) CO.,LTD**  
**Block A,No.7 Yongxin Street,Qunlian Village,Tanzhou Town,**  
**Zhongshan, Guangdong, 528467, CHINA**

The Establishment Registration and Device Listing information is as below:

Owner/Operator Number:	10077647
Establishment Registration Number:	3017494121

Listing No.	Product code:	Product name:
D417882	IWP	Radiographic protective Glove

Please inform us of any changes to:

- the company information
- additional generic groups of devices or additional devices
- discontinuation of a generic group of devices or devices

We strongly recommend you to contact us via email [info@medright-tech.com](mailto:info@medright-tech.com) to update the information every year.

If you have any queries regarding regulation, please do not hesitate to contact us.

Yours sincerely,

DRLM Home (mainMenu.htm)

 Facility

 Products Listing

## Annual Registration Successful

Facility: RIDER BULL BIO-TECHNIQUE (ZHONGSHAN) CO.,LTD, Zhongshan, Guangdong, CHINA

You have successfully updated your registration and listing information for 2021.

Your registration will be valid through Dec 31, 2021.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2021.

Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.

You may contact the FDA with any questions at [regis@cdrh.fda.gov](mailto:regis@cdrh.fda.gov).

The Owner/Operator Number for this Registration is: 10077647.

## Facility Information

Registration Number: 3017494121  
 Initial Importer: N  
 Facility Name: RIDER BULL BIO-TECHNIQUE (ZHONGSHAN) CO.,LTD  
 Address: Block A,No.7 Yongxin Street,Qunlian Village,Tanzhou Town, Zhongshan, Guangdong, 528467, CHINA  
 DUNS Number:  
 Foreign Trade Zone: N  
 Facility URL:  
 Other Business Trade Name(s):

## Owner/Operator Information

Owner/Operator Number: 10077647  
 Contact Name: Chen Gengdong  
 Company: RIDER BULL BIO-TECHNIQUE (ZHONGSHAN) CO.,LTD  
 Address: Block A,No.7 Yongxin Street,Qunlian Village,Tanzhou Town Zhongshan, GUANGDONG, 528467, CHINA  
 Telephone: 86 - 760 - 8672688 - 8  
 Fax: -  
 E-mail: [xinchengqz@sina.com](mailto:xinchengqz@sina.com)  
 DUNS Number:

## Official Correspondent Information

Contact Name: Chen Gengdong  
 Company: RIDER BULL BIO-TECHNIQUE (ZHONGSHAN) CO.,LTD  
 Address: Block A,No.7 Yongxin Street,Qunlian Village,Tanzhou Town Zhongshan, GUANGDONG, 528467, CHINA  
 Telephone: 86 - 760 - 8672688 - 8  
 Fax: -  
 E-mail: [xinchengqz@sina.com](mailto:xinchengqz@sina.com)  
 DUNS Number:

## United States Agent Information

Contact First Name: Jeff  
 Contact Last Name: Zhang  
 Contact Title: Mr  
 Business Name: MEDRIGHT TECH INC  
 Address: 13525 40TH RD STE 3F Flushing, New York, 11354, UNITED STATES  
 Phone: 917 - 4801489  
 Fax:  
 DUNS Number:  
 E-mail: [info@medright-tech.com](mailto:info@medright-tech.com)

## Device Listings

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities	Importers

2021/1/13

Confirmation Page

D417882	510(k) exempt	IWP	Radiographic protective Glove	Contract Manufacturer Foreign Exporter Manufacturer	
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Date of Initial Registration: 2020-09-09 22:25:08.0

ASCEND



Quality Management System Certification  
To Certify

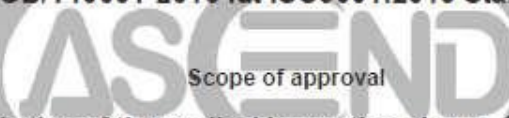
Rider Bull Bio-Technique (Zhongshan) Co.,Ltd.

Registered Address: Block A No.7 Yongxin Street,Qunlian Village  
Tanzhou Town,Zhongshan City

Business Address: Block A No.7 Yongxin Street,Qunlian Village  
Tanzhou Town,Zhongshan City

Its quality management system has passed the certification  
review of ASED, to meet

GB/T19001-2016 idt ISO9001:2015 Standard



Marketing of the medical inspection gloves (Vinyl,  
Nitrile, Vinyl/Nitrile blend) and the disposable  
gloves (Vinyl, Nitrile, Vinyl/Nitrile blend)

Certificate number: ASED2023Q0593R0S

Unified credit social code: 91442000MA51P9TX27

Certificate of the issuance date: 12 Oct.2023

Certificate of the effective date: 1 Oct.2023

The authentication manager: Aman Cai



This certificate issued by Shanghai Ascend Certification&Technical Co.,Ltd. The certificate is only valid with related permits when appropriated. The certificated organization must successful pass the annual surveillance audit to maintain the validity after the certificated approval date. It should be returned if the management system of certificated organization to fail to be in conformity with the certification standard. The effectiveness of the certification qualification can be log on [www.ascendchina.com.cn](http://www.ascendchina.com.cn) to query. Certificate information also can inquire on <http://cx.cnca.cn> by national certification and accreditation.

Ascend Certification

Address:19B Yindong building, No.55 Xinjinqiaoroad, Pudong, Shanghai(China free trade area)

ASCEND



Quality Management System Certification  
To Certify

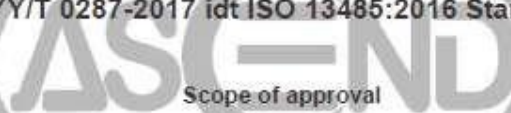
Rider Bull Bio-Technique (Zhongshan) Co.,Ltd.

Registered Address: Block A No.7 Yongxin Street,Qunlian Village  
Tanzhou Town,Zhongshan City

Business Address: Block A No.7 Yongxin Street,Qunlian Village  
Tanzhou Town,Zhongshan City

Its quality management system has passed the certification  
review of ASCED, to meet

YY/T 0287-2017 idt ISO 13485:2016 Standard



Scope of approval

Marketing of the medical inspection gloves  
(Vinyl, Nitrile, Vinyl/Nitrile blend)

Certificate number: ASEDC2020Q0504R05

Unified credit social code: 91442000MA51P9TX27

Certificate of the issuance date: 12 Oct.2020

Certificate of the effective date: 12 Oct.2023

The authentication manager:



This certificate issued by Shanghai Ascend Certification&Technical Co.,Ltd. The certificate is only valid with related permits when appropriated. The certificated organization must successful pass the annual surveillance audit to maintain the validity after the certificated approval date. It should be returned if the management system of certificated organization to fail to be in conformity with the certification standard. The effectiveness of the certification qualification can be log on [www.ascendchina.com.cn](http://www.ascendchina.com.cn) to query. Certificate information also can inquire on <http://cx.cnca.cn> by national certification and accreditation.

Ascend Certification

Address:198 Yindong building,No.58,Xinjinqiaoroad,Pudong,Shanghai(China free trade area)

# EC REP CERTIFICATE



## CMC MEDICAL DEVICES & DRUGS SL NO. CMC/CE/2020/28102020.5

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L Is the European Authorized Representative of

**Rider Bull Bio-Technique(Zhongshan)Co.,LTD.  
Block A ,NO.7 Yongxin Street, Qunlian Village, Tanzhou Town,  
Zhongshan City**

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.

The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 93/42/EEC on medical devices as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/2478/2020**



Issued on: 28/10/2020

Valid until: 27/10/2021

  
Authorized Signatory  
CMC Medical Devices & Drugs SL

# EC REP CERTIFICATE



ANNEX I Medical Device Products



Disposable Medical vinyl/nitrile blend Examination Gloves

Disposable Medical nitrile Examination Gloves

