



## **Fiscal Year 2020**

# **CERTIFICATION OF REGISTRATION**

This certifies that:

**ZHENGZHOU RUIPU MEDICAL TECHNOLOGY CO., LTD**

**13th Floor, Building A, Dianshang Building, Huanan 2 Road, Longhu  
Town, Xinzheng City, Zhengzhou City, HENAN, 451150, CHINA**

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

**HEALREG SERVICE INC**

**Owner/Operator Number: 10062918**

**Device Listing#: See annex**

*HEALREG 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. HEALREG 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. HEALREG 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, HEALREG SERVICE INC is not affiliated with the U.S. Food and Drug Administration.*



A handwritten signature in black ink, appearing to read "Sim / n", written over a horizontal line.

Chief engineer

Issued: March 13, 2020

Expiration Date: December 31, 2020



CERTIFICATION  
EUROPE (HONG KONG)

# Certificate of Registration

Certificate NO: 10136571Q

This is to Certify that the Quality Management System of

## Zhengzhou Ruipu Medical Technology Co., Ltd.

Layer 13, Building A, Electrical Business Building, Huanan 2<sup>nd</sup> Road,  
Longhu Town, Xinzheng City, Zhengzhou City, He'nan Province, China

Has been audited to the following Quality Management System standard:

### ISO9001:2015

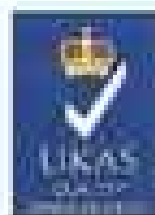
This system is valid for the

Technical development of medical equipment; Production and sales  
of class I, II medical equipment, medical reagents, disinfection supplies  
(except hazardous chemicals), non-woven fabrics and products, labor  
insurance supplies; Internet technology development service; Cultural  
and art exchange activities planning

Date of issue: Mar. 18, 2020

Date of expiry: Mar. 18, 2023

This certificate will not remain valid only if the certified organization  
accepts at least one surveillance audit annually within the validity  
period of the certificate in which the surveillance audit conforming  
mark is in the designated position on the certificate.



Issued by:

*Immo*

12months

24months







# Certificate of Compliance

No. 1P200318.ZRMUS34

Certificate's  
Holder:

Zhengzhou Ruipu Medical Technology  
Co. Ltd.

13th Floor, Building A, Dianshang Building, Huanan  
2 Road, Longhu Town, Xinzheng City, Zhengzhou  
City, Henan Province.

Certification ECM  
Mark:



Product:  
Model(s):

Disposable protective mask  
Disposable Protective mask,  
Disposable kn95 mask

Verification to:

Standard:  
EN 149:2001+A1:2009

related to CE Directive(s):  
R 2016/425 (Personal Protective Equipment)

**Remark:** This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:



The manufacturer is responsible for the CE Marking process. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01\_ECM rev.3 available at: [www.entecerma.it](http://www.entecerma.it)

**Issuance date: 18 March 2020**

**Expiry date: 17 March 2025**

Reviewer  
Technical expert  
Amanda Payne



Approver  
ECM Service Director  
Luca Bedonni







# Certificate of Compliance

No. 1P200318.ZRMUS33

Certificate's  
Holder:

Zhengzhou Ruipu Medical Technology  
Co. Ltd.

13th Floor, Building A, Dianshang Building, Huanan  
2 Road, Longhu Town, Xinzheng City, Zhengzhou  
City, Henan Province.

Certification ECM  
Mark:



Product:  
Model(s):

Protective mask  
KN90, KN95, KN100

Verification to:

Standard:  
EN 149:2001+A1:2009

related to CE Directive(s):  
R 2016/425 (Personal Protective Equipment)

**Remark:** This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

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**Issuance date:** 18 March 2020

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Reviewer  
Technical expert  
Amanda Payne

Approver  
ECM Service Director  
Luca Bedonni



统一社会信用代码

91410184MA481F657Y

# 营业执照

(副本)<sup>1-1</sup>



扫描二维码登录  
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信息公示系统”  
了解更多登记、  
备案、许可、监  
管信息。

名称 郑州锐普医疗科技有限公司

注册资本 壹仟万圆整

类型 有限责任公司(自然人投资或控股)

成立日期 2020年02月22日

法定代表人 寇月朋

营业期限 长期

经营范围 医疗器械的技术开发;销售:第一、二类  
医疗器械、医用试剂、消毒用品(危险化  
学品除外)、无纺布及制品;劳保用品的  
生产及销售;互联网技术开发服务;文化  
艺术交流活动策划。涉及许可经营项目,  
应取得相关部门许可后方可经营(依法须  
经批准的项目,经相关部门批准后方可开  
展经营活动)

住所 河南省郑州市新郑市龙湖镇华  
南二路电商大厦A栋13层

登记机关



2020 年 2 月 22 日

国家企业信用信息公示系统网址:  
<http://www.gsxt.gov.cn>

市场主体应当于每年1月1日至5月30日通过国  
家企业信用信息公示系统报送公示年度报告

国家市场监督管理总局监制





## **Fiscal Year 2020 CERTIFICATION OF REGISTRATION**

**Annex to Device Listing# for Owner/Operator Number: 10062918**

<b>Listing No.</b>	<b>Code</b>	<b>Device Name</b>	<b>Proprietary Names</b>	<b>Activities</b>
D374810	MSH	Respirator, surgical	KN100 Mask	Manufacturer Contract Manufacturer Remanufacturer Foreign Exporter
			KN95 Mask	
			KN90 Mask	
			disposable mask	

**END OF THE ANNEX**

A handwritten signature in black ink, appearing to read "Sim / m".

Chief engineer

Issued: March 13, 2020

Expiration Date: December 31, 2020