

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL
PRODUCTS

证书编号：鲁潍食药监械出 20200008

Certificate NO. : Approved by Shandong Weifang food drug safety system20200008

产品名称：医用防护服；一次性使用医用口罩，医用外科口罩，医用防护口罩。

Product (s): Protective clothing for medical use, Disposable Medical Mask, Surgical Mask, Medical Protective Mask.

规格型号：型号连身式、规格 160. 165. 170. 175. 180. 185；挂耳式、系带式，系带式，折叠式。

Model: jumpsuit、specification 160.165.170.175.180.185; Earloop Mask、tie-on mask, tie-on mask, Folded Mask.

产品注册或备案凭证号：鲁械注准 20182640065；鲁械注准 20172640889，鲁械注准 20172640350，鲁械注准 20172640644。

Registration certificate(s): Approved by Shandong(Lu) food drug safety system 20182640065; Approved by Shandong(Lu) food drug safety system20172640889, Approved by Shandong(Lu) food drug safety system20172640350, Approved by Shandong(Lu) food drug safety system20172640644.

生产企业 山东省聚成医疗器械有限公司

Manufacturer: Shandong Jucheng Medical Devices Co., Ltd

生产企业住所：安丘市双丰大道东段南侧

Address of manufacturer: South side of Dongduan, Shuangfeng Dadao, Anqiu City, Weifang, Shandong Province, China, 262100

生产许可或备案凭证号：鲁食药监械生产许 20170021 号

Manufacturing License(s): The permission number of Shandong(Lu) drug safety food machinery20170021

兹证明上述产品已准许在中国生产和销售。

This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至：2022 年 3 月 27 日

This certification valid until: 27/03/2022

备注：无

Remark: None

2020 年 3 月 28 日
(出具单位盖章)



医疗器械生产许可证

许可证编号鲁食药监械生产许 20170021 号

企业名称:山东省聚成医疗器械有限公司

生产地址 安丘市双丰大道东段南侧

法定代表人:黄冠儒

生产范围:Ⅱ类: 6864 医用卫生材料及敷料
※※

企业负责人:王振

住 所:安丘市双丰大道东段南侧

发证部门:山东省食品药品监督管理局

有效期限: 至 2022 年 08 月 09 日

发证日期: 2018 年 05 月 18 日



Certificate

No. ICR Polska/M8406320



Name and address of certificate owner:

Shandong Jucheng Medical Devices Co., Ltd
South side of Dongduan, Shuangfeng Dadao, Anqiu City, Weifang,
Shandong Province

Name and address of manufacturer:

Shandong Jucheng Medical Devices Co., Ltd
South side of Dongduan, Shuangfeng Dadao, Anqiu City, Weifang,
Shandong Province

Product name:

Disposable Mask

Product types:

JC001

This certificate confirms that the product meets the requirements of the following standards and within limits of its standards gives presumption of conformity with essential requirements of Regulation 2016/425

EN 149:2001+A1:2009

The certification process has been carried out in accordance with the program PC-P-07-07.

Evaluation has been carried out in accordance with test reports made by European Quality Test Co., LTD.

No. of test reports:

EQT20(02)3140002-PPE

Certificate issue date:

18.03.2020

Expiration date:

17.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-8463.

This certificate applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standards.



Director: Rafał Kalinowski

Warsaw, 18. 03. 2020

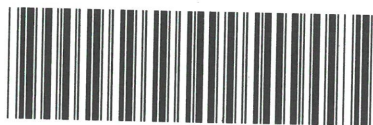


ICR Polska Co. Ltd.

ul. Plac Przymierza 6, 03-944 Warszawa
www.icrpolska.com, e-mail: icrpolska@icrqa.com

TEST REPORT

(Electronic version)



No:200048459

VERIFICATION WEBSITE: www.gtcc.net.cn

VERIFICATION CODE: QNGM-7104-04

检测报告



ISSUE DATE:2020-04-05

APPLICANT: SHANDONG JUCHENG MEDICAL DEVICES CO., LTD
ADDRESS: SOUTH SIDE OF DONGDUAN, SHUANGFENG DADAO, ANQIU CITY, WEIFANG, SHANDONG PROVINCE, CHINA

SAMPLE INFORMATION:

FORTY KN95 PROTECTIVE MASKS

MANUFACTURE'S NAME: SHANDONG JUCHENG MEDICAL DEVICES CO., LTD

DATE RECEIVED/DATE TEST STARTED: 2020-03-28

CONCLUSION:

FILTRATION EFFICIENCY TO NaCl PARTICULATE MATTER

M

INSPIRATORY RESISTANCE

M

EXPIRATORY RESISTANCE

M

HEAD BAND

M

APPEARANCE INSPECTION[2 PIECES]

M

NOTE: "M" -MEET THE STANDARD'S REQUIREMENT "F" -FAIL TO MEET THE STANDARD'S REQUIREMENT
"---" -NO COMMENT

REMARK:

THE AUTHORIZATION OF APPEARANCE INSPECTION IS NOT RECEIVED FROM CNAS.
THIS REPORT IS THE ENGLISH TRANSLATION VERSION OF THE REPORT 200048458.
ALL THE TESTED ITEMS ARE TESTED UNDER THE STANDARD CONDITION (EXCEPT FOR INDICATION).
COPIES OF THE REPORT ARE VALID ONLY RE-STAMPED.
THE EXPERIMENT WAS CARRIED OUT AT No.1, ZHUJIANG ROAD, PANYU DISTRICT, GUANGZHOU, GUANGDONG, P. R. CHINA.

APPROVED BY:

ZiShan Guo SENIOR ENGINEER

郭子山

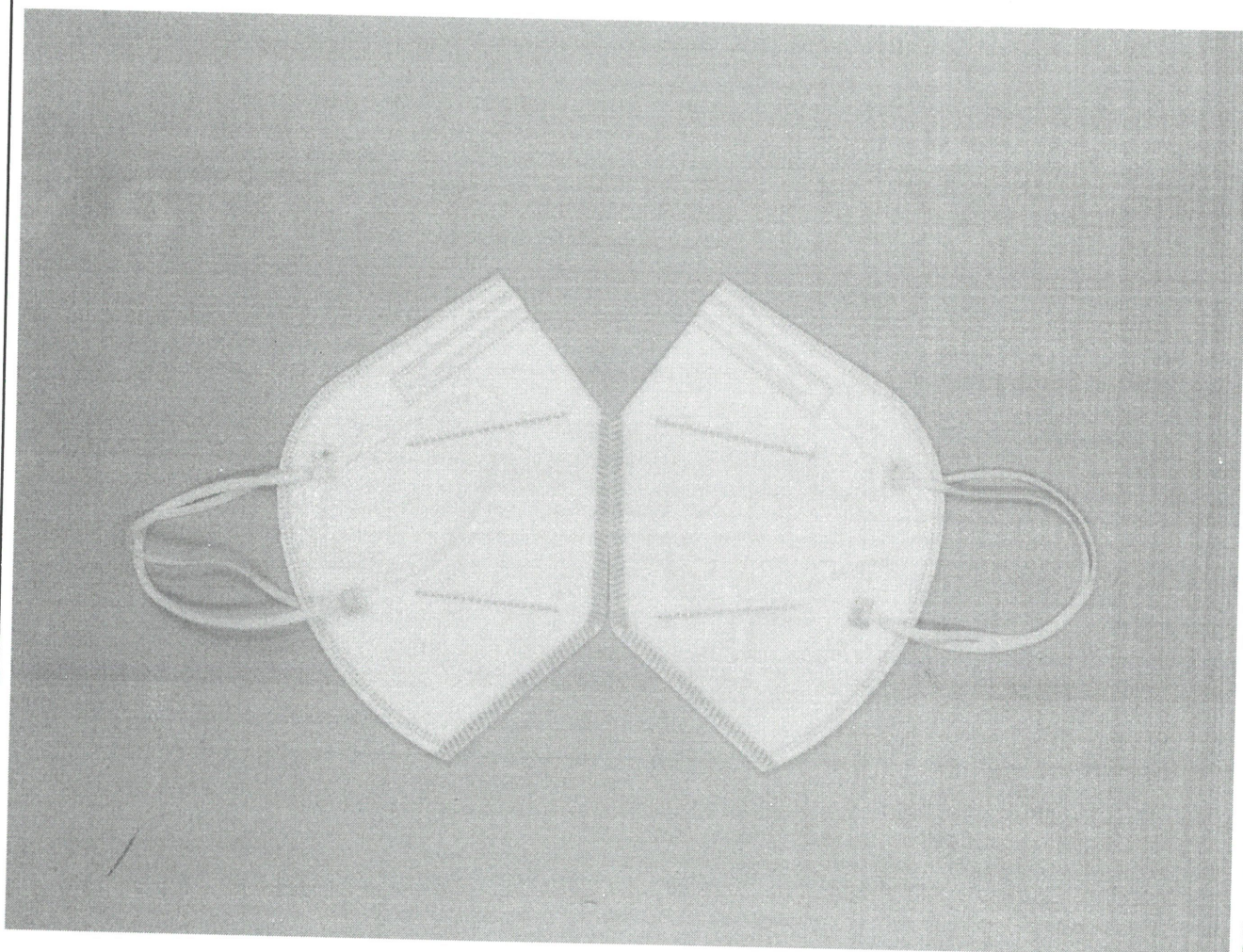


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TEST REPORT

(Electronic version)

No:200048459



TEST REPORT

(Electronic version)

No:200048459

FILTRATION EFFICIENCY TO NaCl PARTICULATE MATTER

(GB 2626-2006 6.3, AIR FLOW:85L/min, AEROSOL:NaCl, AEROSOL CONCENTRATION:15mg/m³,
TEMP:23.0°C, RH:36.0%)

FILTRATION EFFICIENCY (%):

UNTREATED SAMPLE

1# 98.26
2# 98.30
3# 97.98
4# 98.15
5# 98.27
6# 98.12
7# 98.06
8# 97.90
9# 97.88
10# 98.21

CONDITIONING TREATED

1# 97.93
2# 97.72
3# 98.06
4# 97.95
5# 97.83

REQUIREMENT

FILTRATION EFFICIENCY (%):

≥95.0
(KN95)
(GB 2626-2006)

INSPIRATORY RESISTANCE (Pa)

(GB 2626-2006 6.5, HEAD SIZE: MEDIUM)

UNTREATED SAMPLE:

1# 62.8
2# 63.2

PRETREATMENT SAMPLE:

1# 75.6
2# 73.2

REQUIREMENT

≤350
(GB 2626-2006)

EXPIRATORY RESISTANCE (Pa)

(GB 2626-2006 6.6, HEAD SIZE: MEDIUM)

UNTREATED SAMPLE:

1# 51.0
2# 53.3

PRETREATMENT SAMPLE:

1# 68.9
2# 64.4

REQUIREMENT

≤250
(GB 2626-2006)

HEAD BAND

(GB 2626-2006 6.11)

UNTREATED SAMPLE:

1# PASS

CONDITIONING TREATED:

1# PASS

REQUIREMENT

EACH HEAD BAND, BUCKLE AND OTHER ADJUST
PARTS OF MASK SHOULD NOT SLIP OR BREAK
UNDER 10N TENSION FOR 10S.
(GB 2626-2006)


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TEST REPORT

(Electronic version)

No: 200048459

APPEARANCE INSPECTION[2 PIECES]

(GB 2626-2006 6.1)

PASS

REQUIREMENT
ACCORDING TO THE CLAUSE 5.2 OF THE
PRODUCT STANDARD
(GB 2626-2006)



——End of Report——

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