



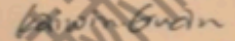
CERTIFICATE OF FDA REGISTRATION

Registration Number : N
Establishment Name : Jiangxi Industrial Co., Ltd.
Establishment Address : Niagb Industrial Park, Ganzhou City,
Jiangxi Province, 342804, China
Owner/Operator Number: 100000
Device Name : MASK, SCAVENGING (Protective Mask)
Product Code : KHA
Device Listing Number : D378043

This certificate only affirms the above stated Establishment has completed the FDA Registration and Device Listing with the US Food & Drug Administration for FY 2020. This certificate issued by Jeston is just to present the registration result on this certificate. 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. No representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." Within the expiration date of this certificate Jeston may confirm the validity of this certificate upon request, unless terminated after issuance of this certificate. Jeston makes no other representations or warranties, nor does this certificate make any warranties or representations to any person or entity other than the named certificate holder, for whose sole benefit it is issued. Jeston assumes no liability to any person or entity in connection with the foregoing. 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 third-party certificate of registration. Jeston is not affiliated with the U.S. Food and Drug Administration.

This registration has been verified as effective within the following date by Jeston.

Registration Expiration Date : 2020-12-31


Jianjun Guan
Certification Service Manager



Niagbo Jeston Certification Service Co., Ltd.

Tel: +86 574 8737 7879 E-Mail: jeston@nbjeston.com Http://www.nbjeston.com



Certificate

No. ICR Polska/M/2020/320



Name and address of certificate owner: Jiangxi [redacted] Industrial CO., Ltd.
Ningdu Shuidong Industrial Park, Ganzhou City, Jiangxi Province, China

Name and address of manufacturer: Jiangxi Hornet Industrial CO., Ltd.
Ningdu Shuidong Industrial Park, Ganzhou City, Jiangxi Province, China

Product name: Protective Mask

Product types: S-KN95

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 PO-P-07-07.

Evaluation has been carried out in accordance with test reports made by Shanghai MICEZ Equipment Testing & Technical Co., LTD Laboratory.

No. of test reports: EQ [redacted] 1-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/2020-8263.

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: Rafal Kalinowski

Warsaw, 18. 03. 2020

ICR Polska Co. Ltd.

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赣州市工业和信息化局

关于同意赣州简美医药科技有限公司等9家企业申报疫情防控急需口罩类医疗器械产品备案的函

市行政审批局：

根据《关于对部分疫情防控急需口罩类第二类医疗器械实施特殊管理的通知》（赣新冠指办明电〔2020〕78号）精神，经企业申请、县（市、区）工信局初步核查，同意赣州简美医药科技有限公司、江西善行智能设备制造公司、赣州美商新材料科技有限公司、赣州博医医用卫生材料公司、赣州圣尼特遮阳科技有限公司、江西赫耐特实业有限公司、赣州福永医疗科技有限公司、赣州市恒工医打器械有限公司、龙南思嘉医疗器械有限公司等9家企业申报疫情防控急需口罩类第二类医疗器械备案，请贵单位按规定予以办理。

特此函达。

附件：口罩项目企业基本情况表



No. F22000005



中国认可
国际互认
检测
TESTING
CNAS L0153



检测报告

TEST REPORT

委托方	江西特实业有限公司
生产单位	江西特实业有限公司
样品名称	3D NANO FACIAL PROTECTIVE MASK
型号规格	S-KN95
检测类别	委托检测



广东产品质量监督检验研究院

GUANGDONG TESTING INSTITUTE OF PRODUCT QUALITY SUPERVISION

检测报告
TEST REPORT



报告随机号: SFX1008

第 1 页 共 4 页

样品名称	3D NANO FACIAL PROTECTIVE MASK		样品编号	YFZ20/004985
	送样 (√)	抽样 (/)		
商标	---		型号规格	S-K395
委托方	江西...实业有限公司		检测类别	委托检测
委托方地址	江西赣州...东工业园		产品编号/批号	---
生产单位	江西...有限公司		抽样单编号	---
受检单位	---		生产日期	---
抽样单位	---		样品数量	50(个)
抽样地点	---		抽样基数	---
抽样日期	---		检验地点	本部实验室
收样日期	2020年03月16日		检验日期	2020年03月16日~ 2020年03月20日
检测依据	GB 2626-2006 《呼吸防护用品 自吸过滤式防颗粒物呼吸器》			
判定依据	---			
检测结论	本次委托检测共检 3 项, 所检项目符合标准的要求。  (检验检测专用章) 签发日期: 2020年03月20日 (QT)			
备注	报告中的“—”表示此项不适用, 报告中“/”表示此项空白。			

检测: 胡斌 审核: 文 主检: 张城正

检测报告

TEST REPORT

第 2 页 共 4 页

序号	检测项目[单位]	标准条款	检测结果	单项结论	备注		
1	过滤效率[%]	5.3	KN95 \geq 95.0	未预处理	合格	/	
							99.8
							99.9
							99.9
							99.8
							99.9
							99.8
							99.8
							99.9
							99.9
							99.8
							99.9
							99.9
							99.9
2	吸气阻力[Pa]	5.5	总吸气阻力 \leq 350	未预处理	合格	/	
							192.6
							206.7
							190.5
预处理	191.3						
	3	5.5	总呼气阻力 \leq 250	未预处理	合格	/	
169.8							
170.5							
168.3							
预处理	167.7						

氯化钠颗粒物检测
温度: (25 \pm 5) °C
湿度: (30 \pm 10) %

实测温度: 26°C
实测湿度: 30%

检测报告
TEST REPORT



附注:

- 1、试验地点: 广州市黄埔区科学城科学大道 10 号
- 2、委托单位地址及邮编: 江西赣州宁都水东工业园
- 3、检测环境条件: 检测项目均在相应标准规定的条件下进行 (有注明的除外)
- 4、抽样程序 (如适用): _____
- 5、偏离标准方法的说明 (如适用): _____
- 6、检测结果不确定度说明 (如适用): _____
- 7、分包项目及分包方 (如适用): _____

江西赫耐特实业有限公司



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ITEM NO.:S-KN95
QTY: 576 PCS
N.W: 2.8 KG
G.W: 6.5 KG
MEAS:64x34.5x46CM
C/NO:
Made In China

江西赫耐特实业有限公司