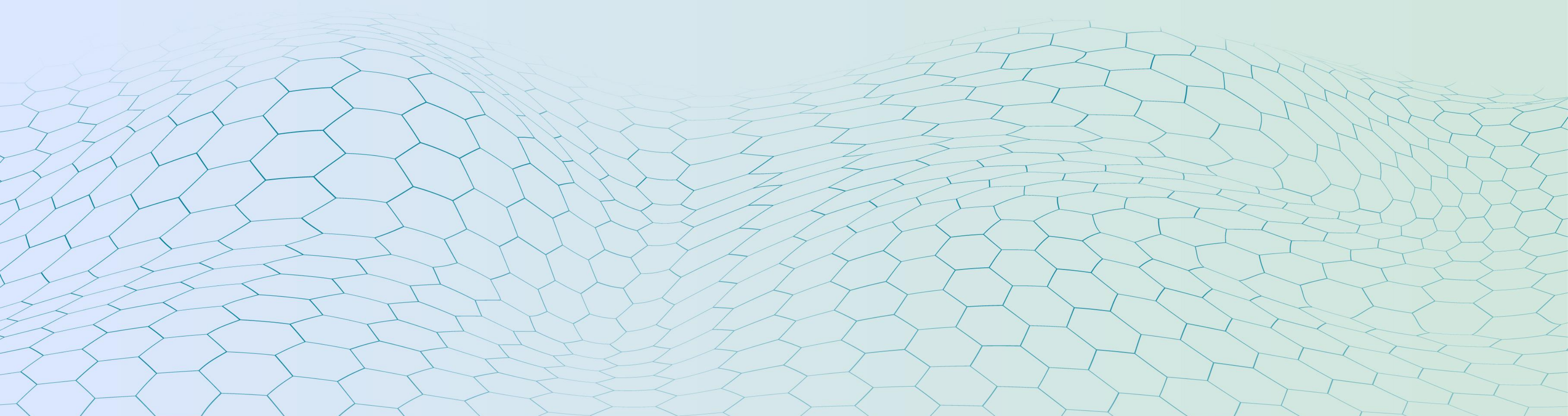


# HanKang KN95/FFP2 FACE MASK





# KN95/FFP2 Face Mask

## PRODUCT INTRODUCTION

Welcome the **KN95/FFP2 Face Mask** with 1 pieces each pack. The KN95/FFP2 Face Mask shares ergonomic design for smooth touch of your face. The KN95 Face Mask adopts national protection level, can effectively protect the external dust and bacteria. Just get our KN95/FFP2 Face Mask, and bring yourself a perfect protection.

# KN95/FFP2 Face Mask

## PACKAGING SPECIFICATIONS

### PARAMETERS

Quantity: 25pc/pack Protection level:KN95/FFP2  
Role: dustproof, anti-fog, antiviral and bacteria

### PACKING LIST

25x KN95/FFP2 Face Mask



# KN95/FFP2 Face Mask

## PACKAGING SPECIFICATIONS

### PARAMETERS


Quantity: 25pc/pack  
Protection level: KN95  
Role: dustproof, anti-fog, antiviral and bacteria

### PACKING LIST

25x KN95 FaceMask



KN95/FFP2 Face Mask  
Certificates



Certificate Number: HW20200322029S  
Personal Protective Equipment Regulation  
(EU) 2016/425

### Certificate Of Compliance

Applicant

: Dongguan Hankang Healthcare Equipment Co., Ltd.

Address

: Building 2, No. 2 E Fang Road, Tingshan, Houjie Town, Dongguan City, Guangdong Province, China

Manufacturer

: Dongguan Hankang Healthcare Equipment Co., Ltd.

Address

: Building 2, No. 2 E Fang Road, Tingshan, Houjie Town, Dongguan City, Guangdong Province, China

Product

: KN95 masks

Model


: 1683


The submitted products have been tested by us with the following standard(s) and found to be in compliance with the listed European Directives.


EN 149: 2001+A1:2009

The test results apply only to the particular sample tested and to the specific tests carried out. Technical Report and documentation are at the Holder's disposal.

This certificate applies specifically to the sample investigated in our test reference number only. The CE markings as shown below can be affixed on the product after preparation of necessary technical documentation. Other relevant Directives have to be observed.





Manager:   
Date: March 22, 2020

Shenzhen Huawin Testing Certification Co., Ltd.

Add: 7F, Building A, Shenye U Center, No. 743, Zhoushi Road, Bao'an District, Shenzhen, China

Http://www.huawinlab.com E-mail: info@huawinlab.com



Fiscal Year 2020  
FDA REGISTRATION CERTIFICATE  
Certificate No.: JF-FDA-0326-0421

Certificate Holder:

DONGGUAN HANKANG HEALTHCARE EQUIPMENT CO.,LTD  
Buildin&2, No. 2 E fan& Road, Tin&shan,Houjie Town, Dongguan,Guangdong, 523900, CHINA

has completed the FDA Establishment Registration (as manufacturer , foreign exporter, contract manufacturer ) and Device Listing with the US Food & Drug Administration.

Registration Number: N

Owner/Operator Number: 10064575

Device Listing:

Device#	Product Codes	Device Name
D379431	LYU	ACCESSORY, SURGICAL APPAREL (Disposable planiformed mask/ Disposable medical mask /N95 filtering face piece respirator )

Registration Expiration Date: 2020-12-31

J&F TECHNOLOGY SERVICES LLC has verified and declares that the above stated facility is registered with the US Food & Drug Administration, Center for Drug Evaluation and Research, Office of Drug Registration and Listing pursuit to the Code of Federal Regulation 21 CFR 207, on the data state above, and makes no other representations and warranties, nor does this certificate makes other representations and warranties to other person or entity other than the name certificate holder, for whose sole benefit it is issued. J&F TECHNOLOGY SERVICES LLC assumes no liability to any person or entity in connection with the foregoing. J&F TECHNOLOGY SERVICES LLC is a private registration agent and is not affiliated with the US Food and Drug Administration.

J&F TECHNOLOGY SERVICES LLC.

2424 Morris Ave 818 Union

NEW JERSEY 07083

United States





Nº 0003300

第二类医疗器械经营备案凭证

备案编号: 粤东食药监械经营备20200560号

企业名称	东莞市汉康保健器材有限公司
法定代表人	戴福星
企业负责人	戴福星
经营方式	批零兼营
住 所	广东省东莞市厚街镇鹅房路2号二号楼102室
经营场所	广东省东莞市厚街镇鹅房路2号二号楼102室
库房地址	广东省东莞市厚街镇鹅房路2号二号楼102室
经营范围	2002年分类目录:6801, 6803, 6807, 6810, 6815, 6820, 6821, 6822, 6823, 6824, 6825, 6826, 6830, 6831, 6833, 6841, 6845, 6854, 6855, 6856, 6857, 6858, 6863, 6864, 6865, 6866, 6870 2017年分类目录:01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 14, 15, 16, 17, 18, 19, 20, 21, 22



备案部门 (公章)  
  
备案日期: 2020年03月04日



# Certificate of Compliance



No. 5C200402R.SZH0Q22

Certificate's  
Holder:

Shenzhen Zhongyue Health Technology  
Co., Ltd

Room 204, Hanyudasha, Longjing 2nd Road,  
Baoan District, Shenzhen, Guangdong Province

Certification ECM  
Mark:



Product:

KN95 Protective mask

Model(s):

ZY-KF95

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, and if necessary, must refer to a Notified Body. 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: 02 April 2020**

**Expiry date: 01 April 2025**

Reviewer  
Technical expert  
Amanda Payne



Approver  
ECM Service Director  
Luca Bedonni



**Ente Certificazione Macchine Srl**

Via Ca' Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) - ITALY  
☎ +39 051 6705141 📠 +39 051 6705156 ✉ [info@entecerma.it](mailto:info@entecerma.it) 🌐 [www.entecerma.it](http://www.entecerma.it)

# Dongguan Hankang Healthcare Equipment Co.,Ltd

CE Technical documentation of Face Mask

Document No: HG20200430

Issue Date: 20200410

## Declaration of Conformity

**Manufacturer:** Dongguan Hankang Healthcare Equipment Co.,Ltd

**Address:** Building 2, No. 2 E FangRoad, Tingshan,Houjie Town, Dongguan City

**Product:** KN95 Protective Mask (Non-medical)

**Mode:** KN95

**Brand:** Hankang

We here with declare that the above-mentioned products meet the provisions of the following Directives and Standards. All technical documentations are retained under the promise of the manufacturer .

### Directives

**General applicable directives:**

The device is in conformity with the following standard

China standard GB2626-2006 KN95 and equivalent to the standard

EN 149:2001+A1:2009 FFP2 of PPE Regulations (2016/425 / EU) .

**Name:** David Shen

**MeTitle:** Manager of Commerce

**Place:** Dongguan, China





Certificate Number: HW20200322029S  
Personal Protective Equipment Regulation  
(EU) 2016/425

## Certificate Of Compliance

Applicant : Dongguan Hankang Healthcare Equipment Co., Ltd.  
Address : Building 2, No. 2 E Fang Road, Tingshan, Houjie Town,  
Dongguan City, Guangdong Province, China  
Manufacturer : Dongguan Hankang Healthcare Equipment Co., Ltd.  
Address : Building 2, No. 2 E Fang Road, Tingshan, Houjie Town,  
Dongguan City, Guangdong Province, China  
Product : KN95 masks  
Model : 1683

The submitted products have been tested by us with the following standard(s) and found to be in compliance with the listed European Directives.

EN 149:2001+A1:2009

The test results apply only to the particular sample tested and to the specific tests carried out. Technical Report and documentation are at the Holder's disposal.

This certificate applies specifically to the sample investigated in our test reference number only. The CE markings as shown below can be affixed on the product after preparation of necessary technical documentation. Other relevant Directives have to be observed.

CE



Manager: GUY SH  
Date: March 22, 2020

Shenzhen Huawin Testing Certification Co., Ltd.  
Add: 7F, Building A, Shenye U Center, No. 743, Zhoushi Road, Bao'an District, Shenzhen, China  
Http://www.huawinlab.com E-mail: info@huawinlab.com



## Fiscal Year 2020 FDA REGISTRATION CERTIFICATE

Certificate No.: JF-FDA-0326-0421

### Certificate Holder:

**DONGGUAN HANKANG HEALTHCARE EQUIPMENT CO.,LTD**

Building 2, No. 2 E Fang Road, Tingshan, Houjie Town, Dongguan, Guangdong, 523900, CHINA

has completed the FDA Establishment Registration (as manufacturer, foreign exporter, contract manufacturer) and Device Listing with the US Food & Drug Administration.

### Registration Number: N

**Owner/Operator Number: 10064575**

### Device Listing:

Device#	Product Codes	Device Name
D379431	LYU	ACCESSORY, SURGICAL APPAREL (Disposable planiformed mask/ Disposable medical mask /N95 filtering face piece respirator )

Registration Expiration Date: 2020-12-31

J&F TECHNOLOGY SERVICES LLC has verified and declares that the above stated facility is registered with the US Food & Drug Administration, Center for Drug Evaluation and Research, Office of Drug Registration and Listing pursuant to the Code of Federal Regulation 21 CFR 207, on the data state above, and makes no other representations and warranties, nor does this certificate makes other representations and warranties to other person or entity other than the name certificate holder, for whose sole benefit it is issued. J&F TECHNOLOGY SERVICES LLC assumes no liability to any person or entity in connection with the foregoing. J&F TECHNOLOGY SERVICES LLC is a private registration agent and is not affiliated with the US Food and Drug Administration.

J&F TECHNOLOGY SERVICES LLC.

2424 Morris Ave 818 Union

NEW JERSEY 07083

United States



## 第二类医疗器械经营备案凭证

Nº 0003300

备案编号: 粤东食药监械经营备20200560号

企业名称	东莞市汉康保健器材有限公司
法定代表人	戴福星
企业负责人	戴福星
经营方式	批零兼营
住 所	广东省东莞市厚街镇鹅房路2号二号楼102室
经营场所	广东省东莞市厚街镇鹅房路2号二号楼102室
库房地址	广东省东莞市厚街镇鹅房路2号二号楼102室
经营范围	2002年分类目录:6801, 6803, 6807, 6810, 6815, 6820, 6821, 6822, 6823, 6824, 6825, 6826, 6830, 6831, 6833, 6841, 6845, 6854, 6855, 6856, 6857, 6858, 6863, 6864, 6865, 6866, 6870 2017年分类目录:01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 14, 15, 16, 17, 18, 19, 20, 21, 22



备案部门 (公章)



备案日期: 2020年3月24日