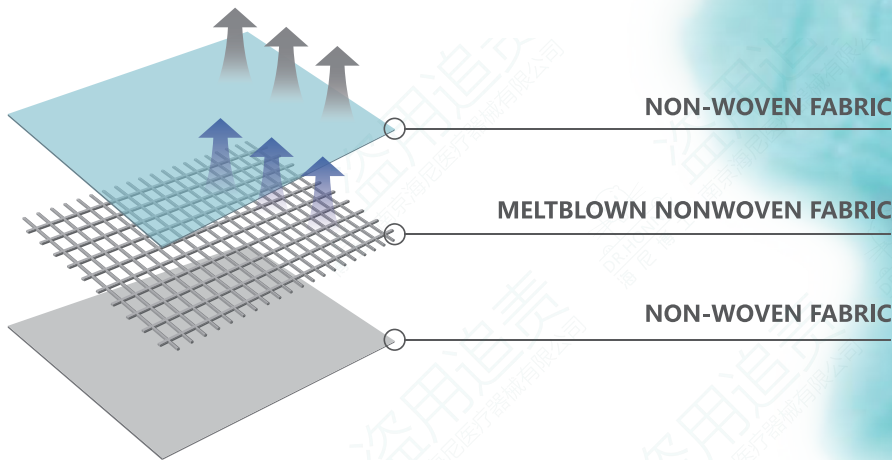




PROTECTION SERIES PRODUCTS



# TYPE I / IIR

DISPOSABLE MEDICAL MASK

**Size :** 175×95MM  
**Model :** MM04 / MM01  
**Filteration Efficiency :**  
BFE ≥95% / ≥98%

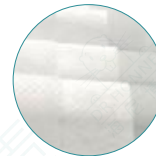


# TYPE I / II

DISPOSABLE MEDICAL MASK

**Size :** 175×95MM  
**Model :** MM02 / MM03  
**Filteration Efficiency :**  
BFE ≥95% / ≥98%





# TYPE IIR

## DISPOSABLE SURGICAL MASK

**Size :** 175×95MM

**Model :** WK01

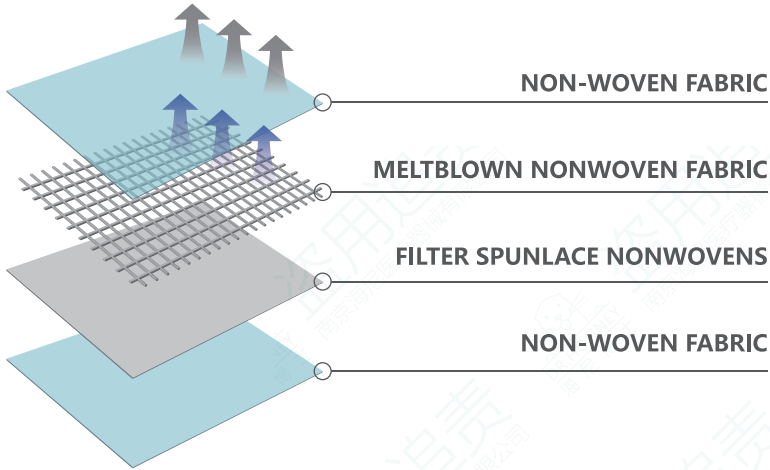
**Filteration Efficiency :**

BFE ≥98%

### PACKING INFORMATION

Model	Description	Qty. per box	Qty. per Carton
MM01	Type IIR	50 PC	2000 PCS
MM02	Type I	50 PC	2500 PCS
MM03	Type II	50 PC	2500 PCS
MM04	Type I	50 PC	1500 PCS
WK01	Type IIR	50 PC	2500 PCS





# FFP3 NR

## FILTERING HALF MASK

Size : 155×105MM  
Model : ZD03  
Filtration Efficiency : PFE≥99%







## FFP2 NR

DISPOSABLE PROTECTIVE MASK

**Size :** 155×105MM

**Model :** ZD01

**Filtration Efficiency :** PFE≥94%



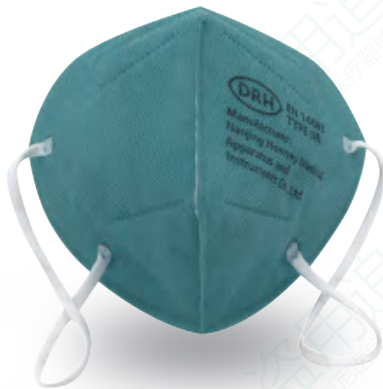
## KN95

PROTECTIVE MASK

**Size :** 155×105MM

**Model :** ZD01

**Filtration Efficiency :** PFE ≥95%



## TYPE IIR

DISPOSABLE MEDICAL MASK

**Size :** 155×105MM

**Model :** ZD02

**Filtration Efficiency :** BFE≥98%

### PACKING INFORMATION

Model	Description	Qty. per box	Qty. per Carton
ZD01	KN95/ FFP2	25 PC	900 PCS
ZD02	TYPE IIR	25 PC	900 PCS
ZD03	FFP3	25 PC	900 PCS
ZD04	FFP1	25 PC	900 PCS



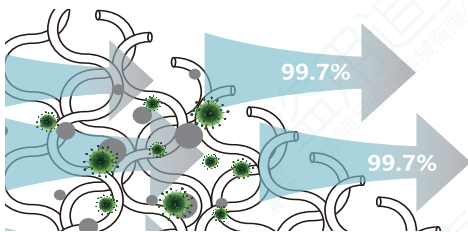
# PTFE TECHNOLOGY NANO MASK

DRH use the latest nano materials as the intermediate filter layer, and the bacteria filtration efficiency is up to 98%. The outer fabric is made of high-density flexible water-repellent fabric to effectively prevent aerosol residue. The inner fabric is made of high support skin-friendly fabric, which effectively protects the facial skin from irritation.



● Aerosol Residue

● Bacteria

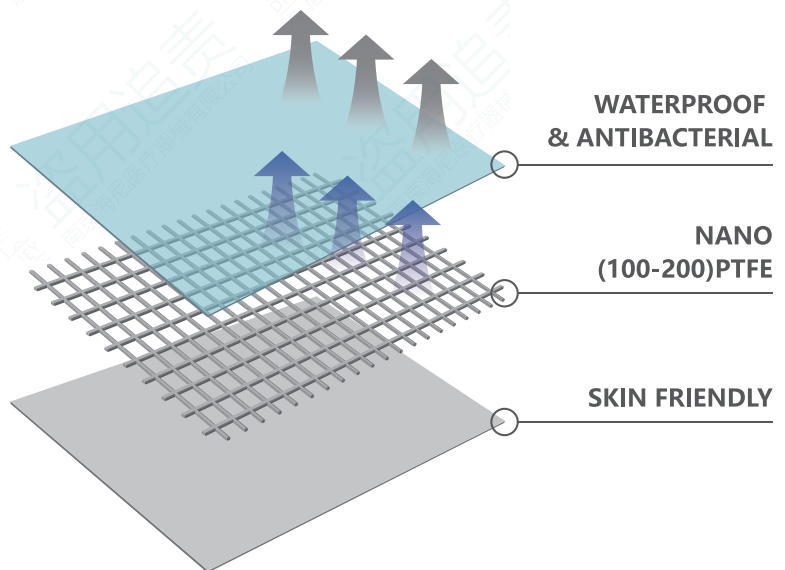


## Material

Inner layer fabric: 100% Cotton  
 Middle layer: PTFE nano membrane  
 Outer layer fabric: 100% Polyester

## Fitting Sketch

1. Take out the mask, with one end of nose clip upward, gently pull the mask belt at both ends and hang it on both ears to avoid the hand contacting the inner layer of the mask.
2. Press the nose clip lightly to make it fit with the bridge of nose, press and hold the nose clip, and adjust to make the mask cover the mouth, nose and jaw.





## PACKING INFORMATION

Description	Qty. per box	Qty. per Carton
Adult	40 PCS	480 PCS
Children's	40 PCS	480 PCS

# REUSABLE NANO MASK

**Material :** Inner layer fabric: 100% Cotton  
Middle layer : PTFE Nano membrane  
Outer layer fabric: 100% Polyester

**Model :** adult / children

**Colour :** black, blue, red, pink, grey

**Sterility :** non-medical

**Filteration Efficiency :** BFE≥98%



# DISPOSABLE MEDICAL PROTECTIVE CLOTHING

The product is made by cutting and sewing two layers of composite material. The two layers of composite material are polyethylene membrane waterproof and breathable layer and non-woven fabric substrate. The face, cuffs, ankles and waist of the hat are made of rubber or rib fabric, and the front of the body is equipped with a closed tail self-locking zipper.

**Material :** Polyethylene fiber waterproof breathable layer, non - woven fabric

**Style :** Conjoined

**Model :** LB01



## PACKING INFORMATION

Model	Description	Qty. per bag	Qty. per Carton
LB01	160,165,170, 175,180,185	1 PC	30 PCS



# DISPOSABLE MEDICAL ISOLATION GOWN

Sewing or ultrasonic, knitting thread or rubber band cuffs, waist with lace up design, to meet the needs of different shapes.

**Material :** 99% long-fiber polyester  
1% carbon fiber  
SMS non-woven cloth

**Style :** Robe  
**Model :** YG01



## PACKING INFORMATION

Model	Description	Qty. per bag	Qty. per Carton
YG01	L,XL,XXL	1 PC	80 PCS

# SURGICAL GOWN

## REUSABLE TYPE

Used to wear on surgeons and wipe nurses to prevent the spread of skin scraps from doctors to open surgical wounds and the body fluids of surgical patients from spreading to medical personnel, thus playing the role of two-way biological protection.

Structure composition: 99% long fiber polyester fiber, 1% carbon fiber material, with rubber band at the cuff and long fiber polyester fiber tie on the back.

If the product is not sterilized before leaving the factory, it must be cleaned and steam sterilized by the user, and can be reused.

**Note :** This product must be washed, disinfected and sterilized before use  
Bleaching agents containing chlorine are prohibited  
Do not iron directly with an iron

### PACKING INFORMATION

Model	Description	Qty. per bag
BF	L,XL,XXL	1 PC
GF	L,XL,XXL	1 PC



## BRUSH HAND CLOTHES

Scope of application: used for wearing on the body of anesthesiologists, itinerant nurses, etc. in the operating room, so as to purify the environment of the operating room from indoor personnel pollution.

Scrubs are made up of short sleeve tops and trousers, which have a certain blocking effect on dandruff, and do not have liquid barrier property

**Style :** short sleeve

**Model :** A1, A2

**Product composition:**

A1 is made of polyester fabric

A2 is made of polyester and cotton



### PACKING INFORMATION

Model	Description	Qty. per bag
A1	M, L, XL, XXL, XXXL	1 PC
GF	M, L, XL, XXL, XXXL	1 PC



# ABOUT US

Nanjing Honey Medical Apparatus and Instruments Co., Ltd. is an enterprise specializing in the research & development of medical protective equipment and manufacturing, located in Gaochun Economic Development Zone, Nanjing.

The licensed business items include the production, manufacturing and sales of medical surgical masks that meet the standards of class II medical devices and YY / 0469; KN95 masks that meet the standards of GB2626-2006; protective masks that meet the standards of GB / T32610-2016; protective clothing, surgical clothing, operation sheets that meet the standards of GB / 19082-2009 & YY / T0506; isolation clothing, clean clothing, hand washing clothes and other products that meet the standards of class I medical device production and manufacturing.



## BUSINESS LICENSE



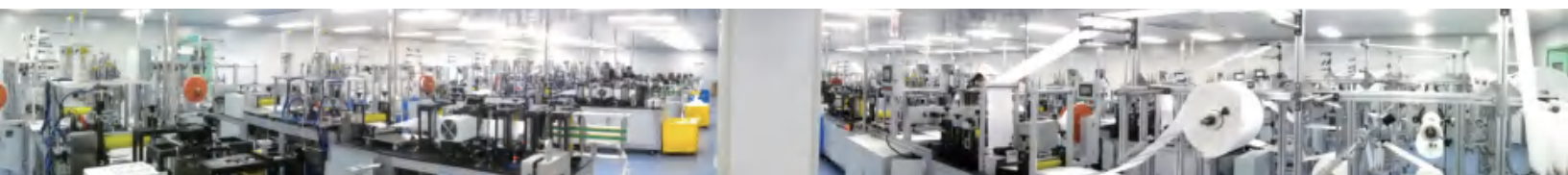
## WHITE LIST



Search for medical supplies and non-medical mask manufacturers that have obtained foreign standard certification or registration

Please enter the Chinese name of the company to search

Company name (Chinese)	Company name (English)	Product Category	Unified social credit code	Foreign registration and certification
Nanjing Haimi Medical Equipment Co., Ltd.	Nanjing Honey Medical Apparatus and Instruments Co., Ltd.	Medical masks	91320118MA20W20949	European Union CE
Nanjing Haimi Medical Equipment Co., Ltd.	Nanjing Honey Medical Apparatus and Instruments Co., Ltd.	Medical protective clothing	91320118MA20W20949	European Union CE
Nanjing Haimi Medical Equipment Co., Ltd.	Nanjing Honey Medical Apparatus and Instruments Co., Ltd.	Non-medical mask	91320118MA20W20949	European Union CE







### MEDICAL DEVICE REGISTRATION CERTIFICATE

**中华人民共和国医疗器械注册证**  
注册证编号：苏械注准应急 20202140029

注册人名称	南京海尼医疗器械有限公司
注册人住所	南京市高淳区经济开发区双高路 68 号
生产地址	江苏省南京市高淳区经济开发区双高路 68 号 4 幢, 江苏省南京市高淳区经济开发区荆山东路 12 号 2 幢 201 室
代理人名称	不适用
代理人住所	不适用
产品名称	医用外科口罩
型号、规格	WK01
结构及组成	医用外科口罩由内层、外层、中间层、口罩带、鼻夹组成。产品以非无菌状态提供，一次性使用。
适用范围	适用于由临床医务人员在有创操作等过程中佩戴
附件	产品技术要求
其他内容	
备注	非无菌产品有效期不超过 2 年。 熔喷布原材料供应商为上海塔迪实业有限公司。

审批部门：江苏省药品监督管理局      核准日期：2020 年 04 月 17 日  
有效期至：2021 年 04 月 16 日

### CLASS I MEDICAL DEVICE FILING DOCUMENT DISPOSABLE MEDICAL ISOLATION GOWN

**第一类医疗器械备案信息表**  
备案号：苏宁械备20200014号

备案人名称	南京海尼医疗器械有限公司
备案人组织机构代码	91320118MA20W2X949
备案人注册地址	南京市高淳区
生产地址	南京市高淳区经济技术开发区荆山路8号-1
产品名称	一次性医用隔离衣
型号/规格	L、XL、XXL
产品描述	隔离衣由99%长纤维聚酯纤维和1%碳纤维材料经裁剪、缝制制成，背为全开口由布带孔穿，非无菌提供，为一次性使用。
预期用途	供医疗机构门诊、病房、检验室等作普通隔离。
备注	
备案单位和日期	南京市市场监督管理局 2020年02月10日
变更情况	

### IOS9001 QUALITY MANAGEMENT SYSTEM CERTIFICATION

**ASQ**  
Quality Management System Certification To Certify  
Nanjing Haini Medical Equipment Co., Ltd.

Registered Address: No. 68, Shuanggao Road, Economic Development Zone, Gaochun District, Nanjing  
Office Address: No. 68, Shuanggao Road, Economic Development Zone, Gaochun District, Nanjing  
Production address: Building 4, No. 68, Shuanggao Road, Gaochun Economic Development Zone, Nanjing City, Jiangsu Province  
Room 201, Building 2, No. 12, Jingxin East Road, Gaochun Economic Development Zone, Nanjing City, Jiangsu Province

Its quality management system has passed the certification review of ASQ, to meet  
**GB/T 19001-2016 idt ISO 9001:2015 Standard**  
Scope of approval  
**Production of Medical Surgical Masks (within the scope of license) and Civil Protective Masks**

Certificate number: ASQ1202003080RM  
Unified credit social code: 91320118MA20W2X949  
Certificate of the issuance date: 13 May 2020  
Certificate of the effective date: 13 May 2020  
The authentication manager: [Signature]

Address: 708 Windong building, No. 68, Shuanggao Road, Gaochun District, Nanjing City, Jiangsu Province, China

### FOREIGN TRADE OPERATION FILING FORM

**对外贸易经营者备案登记表**  
备案登记编号: 01835708      统一社会信用代码: 91320118MA20W2X949

经营者中文名称	南京海尼医疗器械有限公司
经营者英文名称	Nanjing Honey Medical Apparatus and Instruments Co., Ltd.
组织机构代码	91320118MA20W2X949
企业类型	有限责任公司
住所	南京市高淳区经济开发区双高路68号
经营范围(中文)	南京市高淳区经济开发区双高路68号
经营范围(英文)	No.68 Shuanggao Road, Economic Development Zone, Gaochun District, Nanjing, China
联系电话	13913260000
电子邮箱	211500
邮政编码	211500
网站地址	www.hnmed.com
工商登记注册号	2020-0-3
工商登记注册号	

被办理工商登记的企业还须填写以下内容

企业法定代表人姓名	赵华伟	有效证件号	37088119671218888
注册资金	壹仟万元		(折美元)

被办理工商登记的企业(地区)企业或个人工商户(独资投资者)还须填写以下内容

企业法定代表人/个体工商户负责人姓名		有效证件号	
企业资产/个人财产			(折美元)

备注

请按照统一社会信用代码的备案, 并由企业法定代表人或个体工商户负责人签字盖章

2020 年 05 月 11 日



# FILTERING HALF MASK EN149:2001+A1:2009 FFP3

## MODULE B

## MODULE C2

**UNIVERSAL CERTIFICATION**  
NB 2163

### EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-957

Respiratory protective devices, filtering half masks to protect against particles manufactured by Nanjing Honey Medical Apparatus and Instruments Co., Ltd. No.68, Shuanggao Road, Economic Development Zone, Gaochun District, Nanjing, China are tested and evaluated according to

**EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking**

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

**Product Definition**  
Model: ZD03  
Filtering half mask  
Classification: FFP3 NR

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with:

- Issuing an appropriate EU Declaration of Conformity according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.
- Ongoing successful performance in fulfillment of the requirements set out in Personal Protective Equipment Regulation (EU) 2016/425 and harmonized standards, entered by assessments based on Annex 7 (Module C2) or Annex 8 (Module D) of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on 06/07/2020 and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

**CE**  
2163

Sun KACMAZ  
UNIVERSAL CERTIFICATION  
Director

UNIVERSALCERT.COM

**UNIVERSAL CERTIFICATION**  
NB 2163

### CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE-957/01

Respiratory protective devices, filtering half masks to protect against particles manufactured by Nanjing Honey Medical Apparatus and Instruments Co., Ltd. No.68, Shuanggao Road, Economic Development Zone, Gaochun District, Nanjing, China Continues to fulfil the requirements of

**EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking**

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

**Product Definition**

Model	Class	EU Type Examination Certificate		
		Serial No	Date	Issuing NB No
ZD03	FFP3 NR	2163-PPE-957	06.07.2020	2163

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with:

- Issuing an appropriate EU Declaration of Conformity according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on 06/07/2020 and will be valid for one year, until 05/07/2021 if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

**CE**  
2163

Sun KACMAZ  
UNIVERSAL CERTIFICATION  
Director

UNIVERSALCERT.COM

**SGS**

Test Report: SL302020081917X Date: August 06, 2020 Page 2 of 4

Test Result:

**Penetration of Filter Material**  
EN 12181:2019, Filter media: 95 (mm)

Device: 4

**As specified**

Parameter	TR	SR	SR
Leakage	0.1%	0.1%	0.1%
Flow rate	0.1%	0.1%	0.1%

Remark:  
Number of specimens and flow rate refer to parameter of EN 149:2001+A1:2009 clause 7.9.2 penetration of filter material.

APPLICABLE AND INSTRUMENTS CO., LTD.  
ECONOMIC DEVELOPMENT ZONE, GAOCHUN DISTRICT, NANJING, CHINA

Where submitted and identified on behalf of the client as:  
(FFP3) Filtering half mask

1430201410  
EN09419  
NANJING HONEY MEDICAL APPARATUS AND INSTRUMENTS CO., LTD.  
20091105

Substant issues (as requested by applicant):  
Aug 04, 2020  
Aug 04, 2020 - Aug 06, 2020  
Latest observation passed the results shown in this test report refer only to the apparatus tested; for further details, please refer to the following pages.

Test Services (Shanghai) Co., Ltd. Testing Center

Page 1 of 10

**MA** (MAHABRATA)

Test Report

Report No.: [2020] WSZ FHL NO.6681

Product Name: Filtering half mask

Applicant: UNIVERSAL CERTIFICATION AND REGISTRATION SERVICES CO., LTD.

Manufacturer: Nanjing Honey Medical Apparatus and Instruments Co., Ltd.

Test Type: Immersed inspection

Jiangsu Guojin Testing Technology Co., Ltd.  
3F, A101 C, Xingye Building, Qianhai Street, Nanjing, Jiangsu, China

Page 1 of 10

Test Report Form No.: WSZ-FHL-01 (2020-01)

Test Report Form No.: WSZ-FHL-01 (2020-01)





# DISPOSABLE PROTECTIVE MASK EN149:2001+A1:2009 FFP2

**IST CHUANGBIAO TESTING**

Test Report No. 20045264 Web Site: www.jstst.com.cn Page 13 Of 14

Class	Result	Assessment				
			30 Units	95 Units	140 Units	
7.14	Breathing resistance	Pass				
			A	0.5kPa	1.3kPa	1.5kPa
			B	0.5kPa	1.3kPa	1.5kPa
			C	0.5kPa	1.3kPa	1.5kPa
			D	0.5kPa	1.3kPa	1.5kPa
			E	0.5kPa	1.3kPa	1.5kPa
			A	0.5kPa	1.3kPa	1.5kPa
			B	0.5kPa	1.3kPa	1.5kPa
			C	0.5kPa	1.3kPa	1.5kPa
			D	0.5kPa	1.3kPa	1.5kPa
			E	0.5kPa	1.3kPa	1.5kPa
			A	0.5kPa	1.3kPa	1.5kPa
			B	0.5kPa	1.3kPa	1.5kPa
			C	0.5kPa	1.3kPa	1.5kPa
			D	0.5kPa	1.3kPa	1.5kPa
E	0.5kPa	1.3kPa	1.5kPa			

Legend:  
 A: Facing directly ahead  
 B: Facing vertically upwards  
 C: Facing vertically downwards  
 D: Lying on the left side  
 E: Lying on the right side

Overall Rating:  
 PASS  
 FAIL  
 DATA

Test Date: 2020-04-03

IST Testing Service

**MA CNAS**

Test Report (2020) WSZ FHL NO.W0096

Product Name: KN95 Protective Mask  
 Client: Nanjing Honey Medical Apparatus and Instruments Co., Ltd.  
 Manufacturer: \_\_\_\_\_  
 Test Type: Entrusted inspection

Jiangsu Guojian Testing Technology Co., Ltd.

Test result	Single Item decision
82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100	Qualified
0.06%	Qualified
97.2%	Qualified
97.6%	Qualified
97.5%	Qualified
97.8%	Qualified
97.3%	Qualified
97.6%	Qualified
97.5%	Qualified
97.6%	Qualified
96.9%	Qualified
97.7%	Qualified
97.2%	Qualified
97.7%	Qualified

Test result: 122.6, 124.0, 120.1, 96.3, 96.4, 96.2, 96.9

Tested: Passed

Single Item decision: Qualified

Test result: 96.3, 96.4, 96.2, 96.9

Tested: Passed

Single Item decision: Qualified

Test result: 96.3, 96.4, 96.2, 96.9

Tested: Passed

Single Item decision: Qualified

Test result: 96.3, 96.4, 96.2, 96.9

Tested: Passed

Single Item decision: Qualified

Test result: 96.3, 96.4, 96.2, 96.9

Tested: Passed

Single Item decision: Qualified

Test result: 96.3, 96.4, 96.2, 96.9

Tested: Passed

Single Item decision: Qualified

Test result: 96.3, 96.4, 96.2, 96.9

Tested: Passed

Single Item decision: Qualified

Test result: 96.3, 96.4, 96.2, 96.9

Tested: Passed

Single Item decision: Qualified

## KN95 PROTECTIVE MASK GB2626-2006



# DISPOSABLE MEDICAL MASK EN 14683:2019+AC:2009 TYPE IIR ZD02

Test Report No.: Z21654219-R1  
Report Date: 12 May 2020

**SUBJECT** Physical & Microbiological Test

**TEST LOCATION** TÜV SÜD China  
TÜV SÜD Products Testing (Shanghai) Co., Ltd.  
B-34, No. 1999 Du Hu Road, Minhang District  
Shanghai 201108, P.R. China

**CLIENT NAME** Nanjing Honey Medical Apparatus and Instruments Co., Ltd

**CLIENT ADDRESS** No.8-1, Jingshan Road, economic development zone, Gaochun District, Nanjing, China

**TEST PERIOD** 12-Apr-2020-03-May-2020

Prepared By: *Bella Xu*  
(Bella Xu)  
Report Drafter

Authorized By: *[Signature]*  
Authorized Signatory

Note: (1) General Terms & Conditions as mentioned on website. (2) The results relate only to the items tested. (3) The test report shall not be reproduced except in full without the written approval of the laboratory. (4) Without the agreement of the laboratory, the client is not authorized to use the test results for unapproved purposes.

Chemical/Microbiology Laboratory: TÜV SÜD Products Testing (Shanghai) Co., Ltd. 5-34, No. 1999 Du Hu Road, Minhang District, Shanghai 201108, P.R. China. Phone: +86 (21) 6027 6376, Fax: +86 (21) 6027 6343, Email: tsc@cn.tuv.com.cn, Website: www.tuv.com.cn

Regional Head Office: TÜV SÜD Certification and Testing (Shanghai) Co., Ltd. No. 111 Yang Yang Road, Shanghai 201199, P.R. China. Phone: +86 (21) 6027 6376, Fax: +86 (21) 6027 6343, Email: tsc@cn.tuv.com.cn, Website: www.tuv.com.cn

Page 1 of 11

Test Report No.: Z21654219-R1  
Report Date: 12 May 2020

**TEST REPORT**

Sample Description : Disposable medical mask (Sterile)  
Sample Quantity : 50 pieces  
Lot Number/Batch Code : Z002/20200412  
Specification : /  
Size : /  
Type of Mask : /  
Brand Name : /  
Remark: The above information was provided by applicant.

**Summary of Test Results**

No.	Test Item	Test Method	Test Standard Type IIR	Judgement
1	Bacterial Filtration Efficiency (BFE) Test (BFE), %	EN 14683:2019+AC:2019(E) Annex B	≥ 98	Pass
2	Differential Pressure Test (Pa/m <sup>3</sup> )	EN 14683:2019+AC:2019(E) Annex C	< 60	Pass
3	Synthetic Blood Penetration Test (SPa)	ISO 22609:2004	≥ 16.0	Pass
4	Microbial Cleanliness Test (CFU/g)	EN 14683:2019+AC:2019(E) Annex D	≤ 30	Pass

Note: Pass = Meet customer requirements;  
Fail = Fail customer requirements;  
# = No comment;  
N.D. = Not detected.

**Photo of Samples**

Chemical/Microbiology Laboratory: TÜV SÜD Products Testing (Shanghai) Co., Ltd. 5-34, No. 1999 Du Hu Road, Minhang District, Shanghai 201108, P.R. China. Phone: +86 (21) 6027 6376, Fax: +86 (21) 6027 6343, Email: tsc@cn.tuv.com.cn, Website: www.tuv.com.cn

Regional Head Office: TÜV SÜD Certification and Testing (Shanghai) Co., Ltd. No. 111 Yang Yang Road, Shanghai 201199, P.R. China. Phone: +86 (21) 6027 6376, Fax: +86 (21) 6027 6343, Email: tsc@cn.tuv.com.cn, Website: www.tuv.com.cn

Page 2 of 11

Test Report No.: Z21653439  
Report Date: 18 April 2020

**SUBJECT** Physical & Microbiological Test

**TEST LOCATION** TÜV SÜD China  
TÜV SÜD Products Testing (Shanghai) Co., Ltd.  
B-34, No. 1999 Du Hu Road, Minhang District  
Shanghai 201108, P.R. China

**CLIENT NAME** Nanjing Honey Medical Apparatus and Instruments Co., Ltd

**CLIENT ADDRESS** No.8-1, Jingshan Road, economic development zone, Gaochun District, Nanjing, China

**TEST PERIOD** 01-Apr-2020-10-Apr-2020

Prepared By: *Bella Xu*  
(Bella Xu)  
Report Drafter

Authorized By: *[Signature]*  
Authorized Signatory

Note: (1) General Terms & Conditions as mentioned on website. (2) The results relate only to the items tested. (3) The test report shall not be reproduced except in full without the written approval of the laboratory. (4) Without the agreement of the laboratory, the client is not authorized to use the test results for unapproved purposes.

Chemical/Microbiology Laboratory: TÜV SÜD Products Testing (Shanghai) Co., Ltd. 5-34, No. 1999 Du Hu Road, Minhang District, Shanghai 201108, P.R. China. Phone: +86 (21) 6027 6376, Fax: +86 (21) 6027 6343, Email: tsc@cn.tuv.com.cn, Website: www.tuv.com.cn

Regional Head Office: TÜV SÜD Certification and Testing (Shanghai) Co., Ltd. No. 111 Yang Yang Road, Shanghai 201199, P.R. China. Phone: +86 (21) 6027 6376, Fax: +86 (21) 6027 6343, Email: tsc@cn.tuv.com.cn, Website: www.tuv.com.cn

Page 1 of 11

Test Report No.: Z21653439  
Report Date: 18 April 2020

**TEST REPORT**

Sample Description : Disposable surgical mask (Sterile)  
Sample Quantity : 40 pieces  
Lot Number/Batch Code : 20200327  
Specification : WK01  
Size : /  
Type of Mask : Type IIR  
Brand Name : /  
Remark: The above information was provided by applicant.

**Summary of Test Results**

No.	Test Item	Test Standard	Judgement
1	Bacterial Filtration Efficiency (BFE) Test	EN 14683:2019+AC:2019(E) Annex B	Pass
2	Differential Pressure Test	EN 14683:2019+AC:2019(E) Annex C	Pass
3	Synthetic Blood Penetration Test	ISO 22609:2004	Pass
4	Microbial Cleanliness Test	EN 14683:2019+AC:2019(E) Annex D	Pass

Note: Pass = Meet customer requirements;  
Fail = Fail customer requirements;  
# = No comment;  
N.D. = Not detected.

**Photo of Samples**

Chemical/Microbiology Laboratory: TÜV SÜD Products Testing (Shanghai) Co., Ltd. 5-34, No. 1999 Du Hu Road, Minhang District, Shanghai 201108, P.R. China. Phone: +86 (21) 6027 6376, Fax: +86 (21) 6027 6343, Email: tsc@cn.tuv.com.cn, Website: www.tuv.com.cn

Regional Head Office: TÜV SÜD Certification and Testing (Shanghai) Co., Ltd. No. 111 Yang Yang Road, Shanghai 201199, P.R. China. Phone: +86 (21) 6027 6376, Fax: +86 (21) 6027 6343, Email: tsc@cn.tuv.com.cn, Website: www.tuv.com.cn

Page 2 of 11

## DISPOSABLE MEDICAL MASK EN 14683:2019+AC:2009 TYPE IIR WK01





# DISPOSABLE MEDICAL MASK EN 14683:2019+AC:2009 TYPE IIR MM01



**Test Report**

Test Report No.: 轻委2020-06-0079

Applicant: Nanjing Honney Medical Apparatus and Instruments Co., Ltd

Sample Name: Disposable medical mask

Type and Specification: EN14683

Completion Date: 2020-06-16

Guangzhou Quality Supervision and Testing Institute (GQT)

Guangzhou Quality Supervision and Testing Institute (GQT)  
Test Report

Page 1 of 5

Disposable medical mask	Production Date: 2020-05-30
MM1	Lot No.: 20200530
EN14683 Type IIR	Expiration Date: 2022-09-30 (years)
	Contract No.: 4423060203
Nanjing Honney Medical Apparatus and Instruments Co., Ltd	Contract Estimator
	Applied Test
Nanjing Honney Medical Apparatus and Instruments Co., Ltd	Sample Quantity: 15 pieces
Test by applicant	Sampling Date: 2020-06-02
	Completion Date: 2020-06-16

2020-2019-AC:2009 Medical face mask-Requirements and test methods

2020-2019-AC:2009 Medical face mask-Requirements and test methods

Requirements of test reference:

Test items meet the requirements of GB 19083-2019+AC:2009 (Type IIR).

Special filtration efficiency (SFE), ②Dimension of the test apparatus, ③Test method of maintenance "1 time" (The side of the test apparatus was located in the "1 time" mode) SFE test data: 99.96%.

④ Tests are carried out on finished products or samples cut from finished products. The Chinese version of this test report is the standard one, the English version is only for reference.

Verified by: 李石仪 Tested by: 田育涛

Small: Chuanxin Industrial Area, Wuhu, Panyu District, Guangzhou, Guangdong. Address: 441300, Tel: 82294

Guangzhou Quality Supervision and Testing Institute (GQT)  
Test Report

Page 5 of 5



Verified by: 李石仪 Tested by: 田育涛

Small: Chuanxin Industrial Area, Wuhu, Panyu District, Guangzhou, Guangdong. Address: 441300, Tel: 82294



**Test Report**

Test Report No.: 轻委2020-06-0484

Applicant: Nanjing Honney Medical Apparatus and Instruments Co., Ltd.

Sample Name: Disposable medical mask

Type and Specification: MM02/EN14683 type I

Completion Date: 2020-06-28

Guangzhou Quality Supervision and Testing Institute (GQT)



**Test Report**

Test Report No.: 轻委2020-06-0485

Applicant: Nanjing Honney Medical Apparatus and Instruments Co., Ltd.

Sample Name: Disposable medical mask

Type and Specification: MM03/EN14683 type II

Completion Date: 2020-06-28

Guangzhou Quality Supervision and Testing Institute (GQT)

## DISPOSABLE MEDICAL MASK EN 14683:2019+AC:2009 TYPE I / II MM02 / MM03



# DISPOSABLE MEDICAL PROTECTIVE CLOTHING

**GTS** Page 4 of 7 TPJ5200302-104

conform with the procedure outlined by the garment, as can be verified by the "Leakage" test, described in 4.3.2.4.1.

**4.3.2.4.1** Chemical protective clothing, Type 3 and Type 4 shall fulfil the requirements specified in 4.3.4 (Table 3), when combined with suitable protective equipment, i.e. for protection of hands, feet, back, head and/or respiratory tract, according to the manufacturer's instructions and when tested as a complete suit.

The requirements of this clause apply to the garment as a whole including component parts (e.g. gloves, boots, hood or respirator), but are not applied to the garment. The joints and enclosures attaching these components are included within the scope of the document, whereas others for the components are given in other European Standards.

**4.3.2.4.2 Pre-cleaning** Prior to testing, the chemical protective clothing shall be cleaned. If the manufacturer's instructions indicate that cleaning is allowed, Manufacturer's instructions with regard to number of cleaning cycles, cleaning procedure and possible neutralisation of residues shall be observed. If no maximum number of cleaning cycles is indicated, the clothing shall undergo five cleaning cycles.

**4.3.3 Conditioned** All chemical protective clothing shall be conditioned for at least 24 h at the same conditions as listed in 4.3.1.

**4.3.4 Resistance to penetration by liquids**

**4.3.4.1 General and preliminary testing**

**4.3.4.2 Resistance to penetration by liquids (spray test)**

**4.3.4.3 Resistance to penetration by liquids (jet test)**

**4.4 Vleer**

**4.4.1 General**

When a cover is fitted as part of the suit, its design from a respiratory protective device joined to the suit, the cover shall comply with the requirements of 4.1.4 to 4.1.6.

Where anti-leakage components are used or specified in the information supplied by the manufacturer, they shall not have an adverse effect on the health of the wearer, or on the protection of the protective garment.

**4.4.2 Mechanical strength of cover**

The cover shall not be readily damaged in such a way as to be likely to affect the performance of the complete device, when tested in accordance with 7.5 of EN 12941:2006. This test shall be followed by a cover test (EN ISO 17491-1, or per test EN ISO 17491-2), as appropriate.

**GTS** Page 9 of 12 TPJ5200302-106

1 of 12 TPJ5200302-106

Revision File: 02-2004  
of inward leakage of aerosols of fine into suits

7.2 Calculation of total inward leakage

7.2.1 The total inward leakage, L<sub>T</sub>, per suit for suit, shall be calculated in accordance with Equation (3):

$$L_T = \frac{1}{100} \sum_{i=1}^n L_{i, \text{max}}$$

The data reported shall pertain to 10 results from 10 or more suits.

7.2.2 The total inward leakage, L<sub>H</sub>, per human subject for subject shall be calculated in accordance with Equation (3):

$$L_H = \frac{1}{100} \sum_{i=1}^n L_{i, \text{max}}$$

The data reported shall pertain to 3 results from 3 or more subjects.

7.2.3 The total inward leakage, L<sub>0.5</sub>, per occasion for occasion shall be calculated in accordance with Equation (4):

$$L_{0.5} = \frac{1}{100} \sum_{i=1}^n L_{i, \text{max}}$$

The data reported shall pertain to 3 results from 3 occasions.

7.2.4 The total inward leakage, L<sub>10</sub>, per position for test position shall be calculated in accordance with Equation (5):

$$L_{10} = \frac{1}{100} \sum_{i=1}^n L_{i, \text{max}}$$

The data reported shall pertain to 3 results from 3 sampling positions.

7.2.5 The mean total inward leakage per occasion, L<sub>0.5</sub>, per occasion in all position shall be calculated in accordance with Equation (6):

$$L_{0.5} = \frac{1}{100} \sum_{i=1}^n L_{i, \text{max}}$$

The data reported shall pertain to 10 suits (or more).

7.2.6 The average, L<sub>0.5</sub>, of all total inward leakage measurements shall then be calculated as:

## EN14605:2005+A1:2009

## EN ISO 13982-2:2004

**GTT** TEST REPORT

Report No.: 1609054770

**CLIENT:** NAN HONEY MEDICAL APPARATUS AND INSTRUMENTS CO., LTD.  
**ADDRESS:** NO. 8-1, JIJIASHAN ROAD, ECONOMIC DEVELOPMENT ZONE, GAUCHAN DISTRICT, NANJING, CHINA

**TEST OBJECTIVE:** WATER RESISTANCE TEST

**TEST RESULTS:**

Item	Result	Standard
Water Resistance (Static)	100%	EN 13052-2006
Water Resistance (Dynamic)	100%	EN 13052-2006
Water Resistance (Pressure)	100%	EN 13052-2006

**TEST REPORT:** WATER RESISTANCE TEST

**TEST RESULTS:**

Item	Result	Standard
Water Resistance (Static)	100%	EN 13052-2006
Water Resistance (Dynamic)	100%	EN 13052-2006
Water Resistance (Pressure)	100%	EN 13052-2006

**MA** TESTING CENTER

**Final Report**  
Report Number: SDWH-M20200827-1(E)

**Skin Irritation Test of Medical disposable protective clothing**  
According to GB/T 16885.10-2017  
0.9% Sodium Chloride Injection Extract

**Test Results:**

Sample	Inward (Score)	Score-G45 (Weight) Size
01	0/0	0/0
02	0/0	0/0
03	0/0	0/0
04	0/0	0/0
05	0/0	0/0
06	0/0	0/0
07	0/0	0/0
08	0/0	0/0
09	0/0	0/0
10	0/0	0/0

**Sponsor:** Nanjing Honey Medical Apparatus and Instruments Co., Ltd.  
**Address:** No.8-1, Jijishan Road, Economic Development Zone, Gauchan District, Nanjing, China

**Test Report:** SKIN IRRITATION TEST

**Test Results:**

Sample	Inward (Score)	Score-G45 (Weight) Size
01	0/0	0/0
02	0/0	0/0
03	0/0	0/0
04	0/0	0/0
05	0/0	0/0
06	0/0	0/0
07	0/0	0/0
08	0/0	0/0
09	0/0	0/0
10	0/0	0/0

## GB19082-2009

## GB/T 16886



# DISPOSABLE MEDICAL ISOLATION GOWN



**Test Report** (Electronic version)  
Verification Website: www.gtcc.net.cn  
Verification Code: NSCW-1829-54

No: 20R000778 Issue Date: 2020-04-20

Applicant: NANJING HONEY MEDICAL APPARATUS AND INSTRUMENTS CO., LTD  
Address: NO.8-1, JINGSHAN ROAD, ECONOMIC DEVELOPMENT ZONE, GAOCHUN DISTRICT, NANJING, CHINA

Information confirmed by applicant:  
Isolation gown  
Quantity: two pieces

Standard Adopted:  
---

Date Received/Date Test Started: 2020-04-22

Conclusion:  
Static hydrostatic resistance[Shell] \*\*\*  
Water-proof property[Shell] \*\*\*

Note: "M"-Meet the standard's requirement; "F"-Fail to meet the standard's requirement; "-"-No content

Remark:  
All the tested items are tested under the standard condition (except for indication).  
Copies of the report are valid only re-issued.  
The experiment was carried out at No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China

Approved By: **Yuan Liu**  
Yuan Liu Engineer

Page 1 of 3

Guangzhou Inspection Testing and Certification Group Co., Ltd.  
Add: No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China. Tel: +86-20-87970398 87970399



**Test Report** (Electronic version)  
No: 20R000778



Page 2 of 3

Certification Group Co., Ltd.  
Guangzhou, Guangdong, P.R.China. Tel: +86-20-87970398 87970399



**TEST REPORT** (Electronic version)  
No: 20R000778

rossing water pressure:60mbor/min, Temperature of the  
face side tested)

ation tester, TNG08 II Type, Face up, Temperature of the

End of Report

Page 3 of 3

Certification Group Co., Ltd.  
Guangzhou, Guangdong, P.R.China. Tel: +86-20-87970398 87970399

**第一类医疗器械备案信息表**

备案号: 苏宁械备20200028号

备案人名称	南京海尼医疗器械有限公司
备案人组织机构代码	91320118MA2J92204F
备案人注册地址	南京市高淳区
生产地址	南京市高淳区经济开发区湖山路8号-1
产品名称	一次性医用隔离衣
型号规格	YG02-180, YG02-165, YG02-170, YG02-175, YG02-180, YG02-185, YG02-160, YG02-165, YG02-170, YG02-175, YG02-180, YG02-185
产品描述	一次性医用隔离衣由主体SM500g无纺布制成, 无纺布外层经特殊处理, 袖口、领口、帽子弹性收口, 非无菌提供, 一次性使用。
预期用途	在医院机构门诊、病房、检验室等作普通隔离。
备注	
备案单位日期	南京市市场监督管理局 2020年02月18日
变更情况	

**第一类医疗器械备案凭证**

南京海尼医疗器械有限公司:

根据国家法规要求, 对号生产第一类医疗器械: 一次性医用隔离衣予以备案, 备案号: 苏宁械备20200028号。

南京市市场监督管理局  
2020年02月18日

**江苏省第一类医疗器械生产备案凭证**

备案号: 苏宁省药监械生产20200003号

企业名称	南京海尼医疗器械有限公司			
住所	南京市高淳区			
生产场所	江苏省南京市高淳区经济开发区湖山路8号-1			
法定代表人	魏翔	企业负责人	魏翔	
邮编	211300	联系电话	15821904288	
生产范围	新分列目录: 1类: 14-18医护人员防护用品***			
生产产品列表	产品名称	产品备案号	是否获批生产	备注
	一次性医用隔离衣	苏宁械备20200014号	否	/
	一次性医用隔离衣	苏宁械备20200028号	否	/
备案日期	2020年02月23日, 法定代表人: 由 汪中伟 变更为 魏翔 2020年04月23日, 企业负责人: 由 汪中伟 变更为 魏翔 2020年7月23日, 管理责任人: 由 刘朝凤 变更为 魏建建			

## CLASS I MEDICAL DEVICE FILING DOCUMENT DISPOSABLE MEDICAL ISOLATION GOWN

[drhonney.com](http://drhonney.com)



Nanjing Honney Medical Apparatus and Instruments Co., Ltd.  
NO.68,Shuanggao Road,Economic Development Zone,Gaochun District,Nanjing,  
Jiangsu province,China  
E-mail: [info@drhonney.com](mailto:info@drhonney.com)  
Tel: 4001009171