
yoniner
Type IIR
Good health guardian
Medical face mask
Soft and comfortable • Efficient filtration • Effective protection
50 PCS/box


Good health
Medical face mask


yoniner
Medical face mask
Manufacturer: Hangzhou Yoniner Pharmaceutical Co.,Ltd.
Address: No.42, Yangcheng Road Nanyang Economic
Development Zone,Xiaoshan,, Hangzhou
Hotline: 400-0656711
Fax: 0571-82171268
Postcode: 311227
European representative: Lotus NL B.V.
Address: Kyriagin Julianaplein 10, te Verd.
2595AA,The Hague, Netherlands.


yoniner
Medical face mask
Soft and comfortable • Efficient filtration • Effective protection
Executive standard: This product complies with EN14683：2019
Expiry date is 2 years.
Manufacturer: Hangzhou Yoniner Pharmaceutical Co.,Ltd.
Address: No.42, Yangcheng Road Nanyang Economic
Development Zone,Xiaoshan,, Hangzhou
Hotline: 400-0656711
Fax: 0571-82171268
Postcode: 311227
European representative: Lotus NL B.V.
Address: Kyriagin Julianaplein 10, te Verd.
2595AA,The Hague, Netherlands.

TÜVRheinland®

# Certificate

**The Certification Body of**
**TÜV Rheinland LGA Products GmbH**

hereby certifies that the organization

**Hangzhou Yoniner**
**Pharmaceutical Co., Ltd.**
**Nanyang Economic Development Zone**
**Xiaoshan, Hangzhou**
**Zhejiang 311227**
**China**

has established and applies a quality management system for medical devices for the following scope:

**Manufacture and Distribution of Medical Devices**

**(see attachment for products included)**

Proof has been furnished that the requirements specified in

## EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

| | |
|---|---|
| Effective Date: | 2018-11-02 |
| Certificate Registration No.: | SX 60131598 0001 |
| An audit was performed. Report No.: | 15083768 005 |
| This Certificate is valid until: | 2021-08-26 |

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜVRheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date 2018-11-02

Herbert Zhong

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev. 0

# TÜV Rheinland
# LGA Products GmbH
# Tillystraße 2, 90431 Nürnberg

**Attachment to Certificate**
**Registration No.:** SX 60131598 0001
**Report No.:** 15083768 005

**Organization:**
Hangzhou Yoniner
Pharmaceutical Co., Ltd.
Nanyang Economic Development Zone
Xiaoshan, Hangzhou
Zhejiang 311227
China

**Scope:**

Products:

- Wound Plasters
- Wound Dressings
- Sterile Gauzes
- Sterile Bandages
- Sterile First Aid Bandages
- First Aid Kits
- Zinc Oxide Plasters
- Medical Tapes (sports tapes, non-woven tapes, paper tapes, elastic tapes, water proof tapes, PE tapes, silk tapes)
- Cohesive Bandages

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

**Certification Body**

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

**Date:** 2018-11-02

Herbert Zhong

# 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： 浙杭食药监械出 20200276 号
Certificate NO.: 浙杭食药监械出 20200276 号

产品名称：一次性使用医用口罩等产品，见附件（共 1 页）
Product(s): Disposable Medical Face Mask,etc.See Attachment ( 1Page )

规格型号：见附件（共 1 页）
Model: See Attachment ( 1Page )

产品注册或备案凭证号：见附件（共 1 页）
Registration certificate(s): See Attachment ( 1Page )

生产企业：杭州江南世家药业有限公司
Manufacturer: Hangzhou Yoniner Pharmaceutical Co.,Ltd.

生产企业住所：杭州市萧山区南阳经济开发区阳城路 42 号
Address of manufacturer: No.42,Yangcheng Road,Nanyang Economic Development Zone,Xiaoshan,Hangzhou,Zhejiang,China.

生产许可或备案凭证号：浙食药监械生产许 20100314 号
Manufacturing License(s): 浙食药监械生产许 20100314 号

兹证明上述产品已准许在中国生产和销售。该产品出口不受限制，出口医疗器械的企业应当保证其出口的医疗器械符合进口国（地区）的要求。
This is to certify that the above products have been registered to be manufactured and sold in China. The exportation of the product(s) is not restricted. The exporter should assure that exporting medical devices meeting requirements of the importing country(region).

证明有效日期至：2020 年 09 月 30 日
This certification valid until: 2020/09/30

备注：/
Remark: /

Zhejiang Medical Products Administration
（浙江省药品监督管理局）
2020 年 04 月 08 日
（出具单位盖章）

# 附件

## ATTACHMENT

证书编号：浙杭食药监械出 20200276 号　　（共 1 页　第 1 页）

Certificate NO.：浙杭食药监械出 20200276 号　　（Page 1 of 1 Page）

| 序号<br>SN | 产品名称<br>Product(s) | 规格型号<br>Model | 产品注册或备案凭证号<br>Registration certificate(s) |
|---|---|---|---|
| 1 | 一次性使用医用口罩<br>Disposable Medical Face Mask | 型号：非灭菌型<br>规格：175×95mm<br>Model:Non sterilization;<br>Specifications: 175×95mm | 浙械注准 20202141134 |
| 2 | 医用外科口罩<br>Medical surgical Mask | 型号：非灭菌型<br>规格：175×95mm<br>Model:Non sterilization;<br>Specifications: 175×95mm | 浙械注准 20202141144 |
| 空白<br>Blank | 空白<br>Blank | 空白<br>Blank | 空白<br>Blank |

CIBG
*Ministerie van Volksgezondheid, Welzijn en Sport*

> Retouradres Postbus 16114 2500 BC Den Haag

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

**Farmatec**

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

**Inlichtingen bij:**
F.J.J. de Bas

medische_hulpmiddelen@minvws.nl

**Ons kenmerk:**
CIBG-20200693

**Bijlagen**
-

**Uw aanvraag**
18 maart 2020

*Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.*

Datum: 24 maart 2020
Betreft: aanmelding medisch hulpmiddel klasse I

Geachte heer Wei,

Graag bevestig ik hierbij de ontvangst op 18 maart 2020 van de mededeling ex artikel 5 van het Besluit medische hulpmiddelen (BMH) dat bedrijf Hangzhou Yoniner Pharmaceutical Co.,Ltd met Europees gemachtigde Lotus NL B.V. onderstaand medisch hulpmiddel, ingedeeld in risicoklasse I, aflevert. Het product is onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie betreffende dit product het bijbehorende kenmerk te vermelden.

**Disposal Surgical Masks**
**(geen merknaam) (NL-CA002-2020-49712)**

Toekomstige wijzigingen in bovengenoemde gegevens – waaronder een eventuele wijziging van de indeling in risicoklasse in verband met wijzigingen van Europese regelgeving inzake de classificatie van medische hulpmiddelen, en aan voortschrijdend wetenschappelijk inzicht (zie art.9, lid 3 van Europese Richtlijn 93/42/EEG) – dient u te zijner tijd mede te delen.

Volledigheidshalve wijs ik u erop dat het - ongeacht uw mededeling – verboden is een medisch hulpmiddel ter aflevering voorhanden te hebben, dan wel af te leveren indien niet aan de voor dat medisch hulpmiddel geldende regels gesteld bij of krachtens de Wet op de Medische Hulpmiddelen (WMH) wordt voldaan. Met name wijzen wij u op de Nederlandse-taaleis, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Market Surveillance- en vigilantiesysteem.

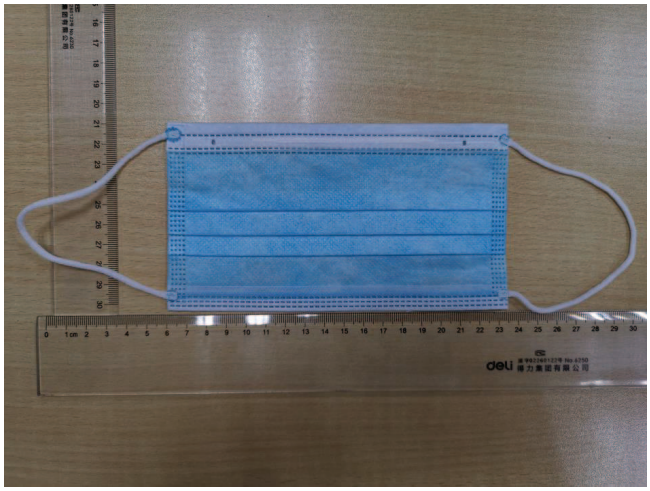
Tevens wijs ik u er voor de goede orde nog op dat de registratie van uw mededeling betreffende de aflevering van het bovengenoemde product slechts een administratieve handeling betreft. Deze ontvangstbevestiging behelst dan ook geen besluit betreffende de kwalificatie van het desbetreffende product als medisch hulpmiddel in de zin van art. 1 WMH, noch betreffende de indeling in risicoklasse I.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec


Dhr. M.J. van de Velde

| | | | | |
|---|---|---|---|---|
| **Prüfbericht-Nr.:** *Test Report No.*: | **50356271 001** | **Auftrags-Nr.:** *Order No.*: | **244225609** | Seite 1 von 16 *Page 1 of 16* |
| **Kunden-Referenz-Nr.:** *Client Reference No.*: | **2158438** | **Auftragsdatum:** *Order date*: | **26.03.2020** | |
| **Auftraggeber:** *Client*: | **Hangzhou Yoniner Pharmaceutical Co., Ltd.** Nanyang Economic Development Zone Xiaoshan Hangzhou 311227 Zhejiang P.R. China | | | |
| **Prüfgegenstand:** *Test item*: | **Medical face mask** | | | |
| **Bezeichnung / Typ-Nr.:** *Identification / Type No.*: | **Type IIR** | | | |
| **Auftrags-Inhalt:** *Order content*: | **Type test** | | | |
| **Prüfgrundlage:** *Test specification*: | **EN 14683:2019+AC:2019** | | | |
| **Wareneingangsdatum:** *Date of receipt*: | 26.03.2020 | | | |
| **Prüfmuster-Nr.:** *Test sample No.*: | A002801382-001 | | | |
| **Prüfzeitraum:** *Testing period*: | 26.03.2020 to 02.04.2020 | | | |
| **Ort der Prüfung:** *Place of testing*: | TÜV Rheinland (Shanghai) Co., Ltd. | | | |
| **Prüflaboratorium:** *Testing laboratory*: | TÜV Rheinland (Shanghai) Co., Ltd. | | | |
| **Prüfergebnis*:** *Test result**: | Pass | | | |



**geprüft von** / *tested by*:

09.04.2020 Rainbow Pan/PE

| **Datum** *Date* | **Name/Stellung** *Name/Position* | **Unterschrift** *Signature* |
|---|---|---|

**kontrolliert von** / *reviewed by*:

09.04.2020 Xiaojun Ding/Reviewer

| **Datum** *Date* | **Name/Stellung** *Name/Position* | **Unterschrift** *Signature* |
|---|---|---|

**Sonstiges** / *Other*:

**Zustand des Prüfgegenstandes bei Anlieferung:** Prüfmuster vollständig und unbeschädigt
*Condition of the test item at delivery*: *Test item complete and undamaged*

| | | | | | |
|---|---|---|---|---|---|
| * Legende: | 1 = sehr gut | 2 = gut | 3 = befriedigend | 4 = ausreichend | 5 = mangelhaft |
| | P(ass) = entspricht o.g. Prüfgrundlage(n) | | F(ail) = entspricht nicht o.g. Prüfgrundlage(n) | N/A = nicht anwendbar | N/T = nicht getestet |
| *Legend:* | *1 = very good* | *2 = good* | *3 = satisfactory* | *4 = sufficient* | *5 = poor* |
| | *P(ass) = passed a.m. test specification(s)* | | *F(ail) = failed a.m. test specification(s)* | *N/A = not applicable* | *N/T = not tested* |

| EN 14683:2019+AC: 2019<br>Medical face masks —<br>Requirements and test methods | |
|---|---|
| **Report Reference No.** ..... : | See cover page |
| **Date of issue** ..... : | See cover page |
| **Total number of pages** ..... : | See cover page |
| **Testing Laboratory** ..... : | **TÜV Rheinland (Shanghai) Co., Ltd.** |
| **Address** ..... : | No.177, 178, Lane 777 West Guangzhong Road, Jing'an District, Shanghai, China |
| **Applicant's name** ..... : | **Hangzhou Yoniner Pharmaceutical Co., Ltd.** |
| **Address** ..... : | Nanyang Economic Development Zone Xiaoshan Hangzhou 311227 Zhejiang P.R. China |
| **Test specification:** | |
| **Standard** ..... : | EN 14683:2019+AC:2019 |
| **Test procedure** ..... : | Type test |
| **Non-standard test method** .....: | N/A |
| **Test Report Form No.** ..... : | EN 14683:2019+AC:2019_A |
| **Test Report Form Originator** ..... : | TÜV Rh (SZ) |
| **Master TRF** ..... : | 2020-03 |
| **Test item description** ..... : | Medical face mask |
| **Trade Mark** ..... : | YN 永宁尔 yoniner |
| **Manufacturer** ..... : | Same as applicant |
| **Model/Type reference** ..... : | Type IIR |
| **Classification** ..... : | Type IIR |

| List of Attachments (including a total number of pages in each attachment): |
|---|
| **N/A** |

| Summary of testing: |
|---|
| **Tests performed (name of test and test clause):**<br><br>Clause 5.2.2 Bacterial filtration efficiency;<br>Clause 5.2.3 Breathability;<br>Clause 5.2.4 Splash resistance;<br>Clause 5.2.5 Microbial cleanliness<br>and construction check were performed on test sample. |

| Copy of marking plate |
|---|
| **The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.**<br><br>**Label:** |

永宁尔 yoniner

# Medical face mask

Type IIR

**Group Name:**

Medical face mask

**Size:**

175*95mm

**The packing way:**

5 / bag

**Structural components:**

1. The mask consists of the mask body, nose clip and mask 2. belt. The body of the mask is made of PP non-woven fabric inside and outside and polypropylene fused jet filter layer in the middle. The nose clip is made of plastic material and the ear band is made of elastic material.

**The product description:**

Surgical mask is a loose-fitting, disposable device that creates a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment.

**Directions for use:**

Open the mask, make sure the skin is dry, stick the inside of the mask to the face, place the nose clip on the bridge of the nose, smooth, spread the mask, cover the nose completely, finally put on the mask belt.

**The period of validity:**

3years

**notes:**

1. The product is for one-time use only, and reuse is prohibited;
2. Do not use if the package is damaged or there is obvious contamination;
3. The product is not provided aseptically and cannot be used in aseptic environment;
4. The product should be used as soon as possible after opening;
5. The mask should be replaced in time after it is wet and contaminated by the patient's blood and body fluids;
6. Please dispose of the product in accordance with the requirements of the clinical waste management ordinance after use

**Transportation and storage:**

1. Keep away from moisture and rain, light and heat during transportation.
2. Storage should be in ventilated, dry, cool, away from heat, non-corrosive gas indoor.

图一 图二 图三

LOT:200307
MFG:2020.03.20
EXP:2025.03.19

**Executive standard:EN 14683:2019**

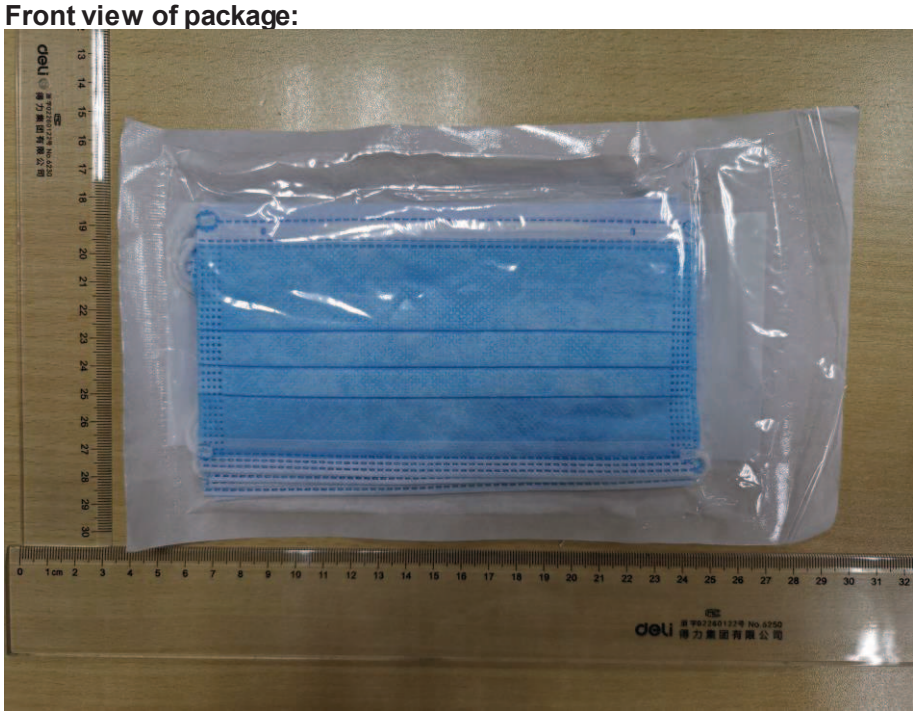
Hangzhou Yoniner Pharmaceutical Co.,Ltd.
Address for visitor: No.42, Yangcheng Road Nanyang Economic Development Zone,Xiaoshan,Hangzhou City,Zhejiang Province
Postcode:311227
The phone:400-0656711
fax:0571-82171268

Made in China

6 940193 801159

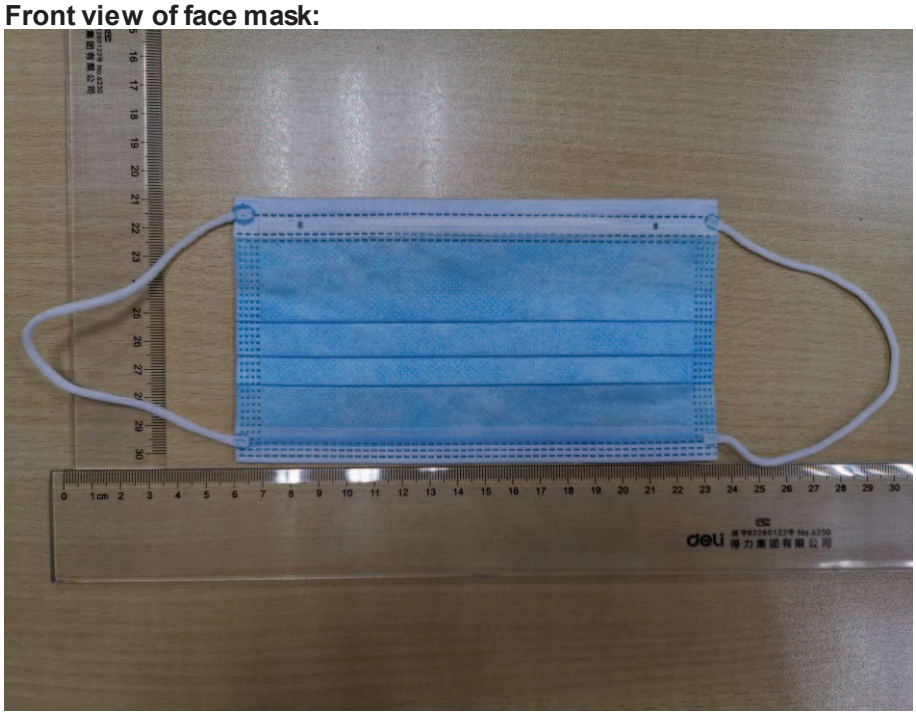
**Box:**


**Front view of package:**

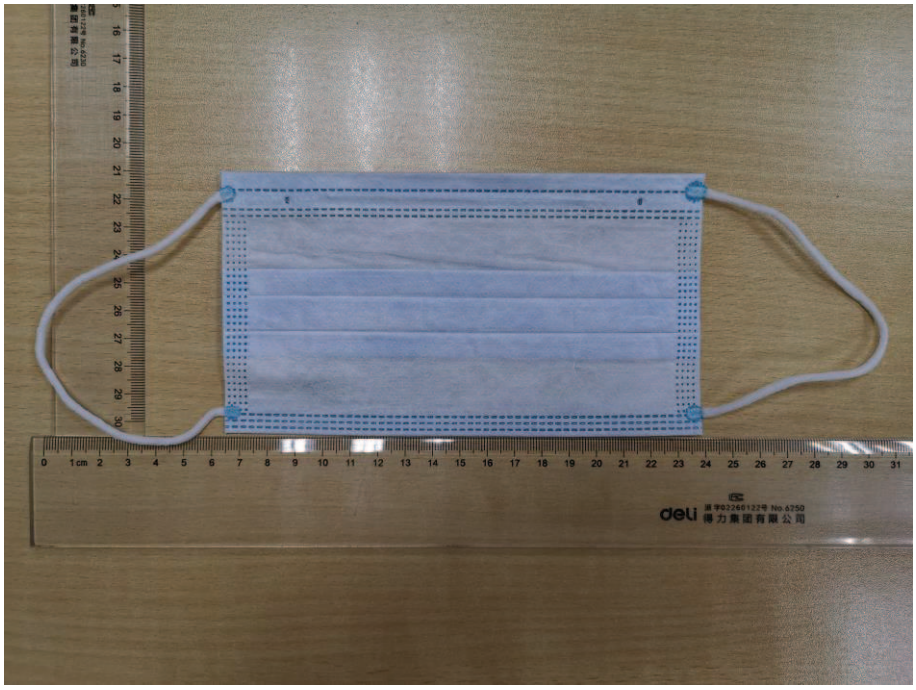


**Back view of package:**

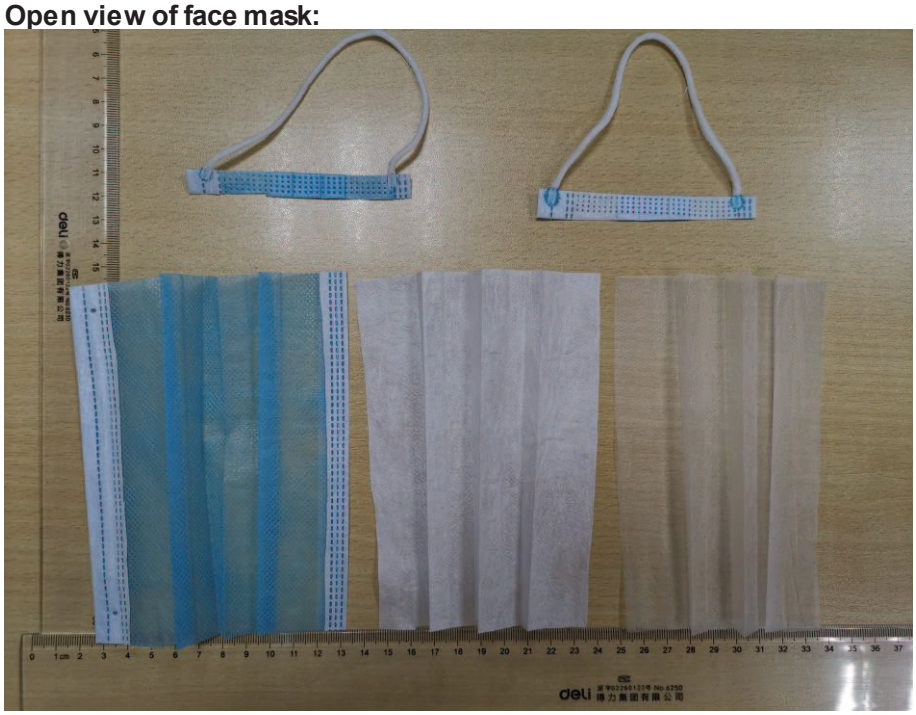

**Front view of face mask:**



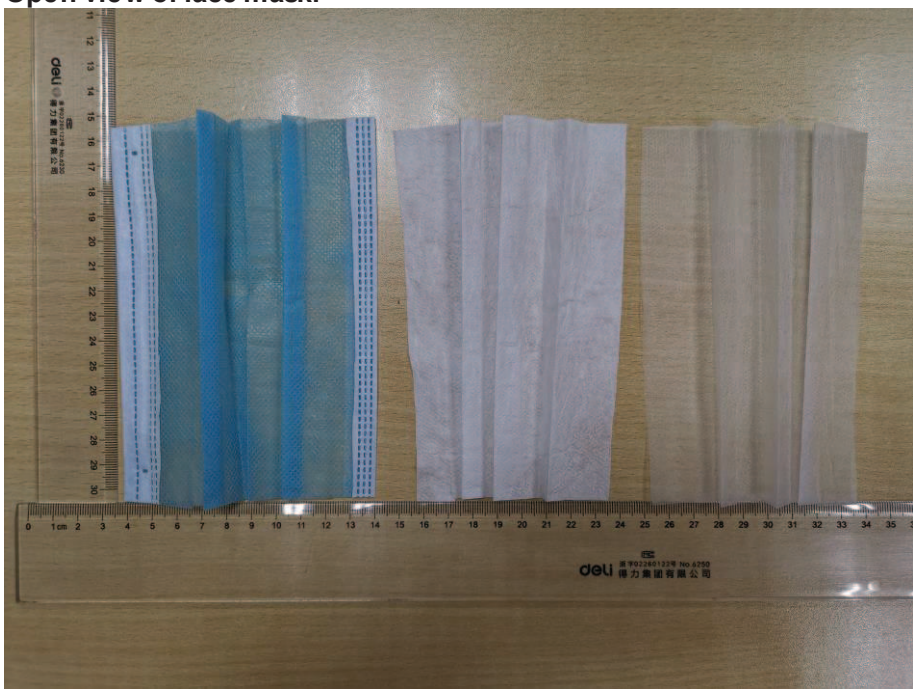
**Back view of face mask:**



**Open view of face mask:**



**Open view of face mask:**



**Testing**

**Date of receipt of test item(s).....:** See cover page

**Dates of tests performed.....:** See cover page

**Possible test case verdicts:**

- test case does not apply to the test object ..... : N/A
- test object does meet the requirement ..... : P (Pass)
- test object was not evaluated for the requirement ... : N/E (collateral standards only)
- test object does not meet the requirement ..... : F (Fail)

**General remarks:**

"(See Attachment #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

**Throughout this report a ☐ comma / ☒ point is used as the decimal separator.**

**Name and address of factory (ies) .....:** Same as applicant

**General product information:**

The submitted samples are type IIR, non-sterile disposable surgical masks which is intended to use as a loose-fitting, disposable device that creates a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment.

| EN 14683:2019+AC:2019 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **4** | **Classification** | | **P** |
| | Medical face masks specified in this European Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant. The 'R' signifies splash resistance. | Type IIR | **P** |
| **5** | **Requirements** | | **P** |
| **5.1** | **General** | | **P** |
| **5.1.1** | **Materials and construction** | | **P** |
| | The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric. | Composed of a filter layer between layers of fabric | **P** |
| | The medical face mask shall not disintegrate, split or tear during intended use. | Complied | **P** |
| | In the selection of the filter and layer materials, attention shall be paid to cleanliness. | Considered | **P** |
| **5.1.2** | **Design** | | **P** |
| | The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides. | Fitted closely over nose | **P** |
| | Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours). | With a nose bridge | **P** |
| **5.2** | **Performance requirements** | | **P** |
| **5.2.1** | **General** | | **P** |
| | All tests shall be carried out on finished products or samples cut from finished products. | Complied | **P** |
| **5.2.2** | **Bacterial filtration efficiency (BFE)** | | **P** |
| | When tested in accordance with Annex B, the BFE of the medical face mask shall conform to the minimum value given for the relevant type in Table 1. | See appended table 5.2.2 | **P** |
| | For thick and rigid masks such as rigid duckbill or cup masks the test method may not be suitable as a proper seal cannot be maintained in the cascade impactor. In these cases, another valid equivalent method shall be used to determine the BFE. | Not thick and rigid mask | **N/A** |

| EN 14683:2019+AC:2019 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | When a mask consists of two or more areas with different characteristics or different layer-composition, each panel or area shall be tested individually. | No such condition | **N/A** |
| | The lowest performing panel or area shall determine the BFE value of the complete mask | | **N/A** |
| **5.2.3** | **Breathability** | | **P** |
| | When tested in accordance with Annex C, the differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 1. | See appended table 5.2.3 | **P** |
| | If the use of a respiratory protective device as face mask is required in an operating theatre and/or other medical settings, it might not fulfil the performance requirements with regard to differential pressure as defined in this European Standard. In such case, the device should fulfil the requirement as specified in the relevant Personal Protective Equipment (PPE) standard(s). | No such respiratory protective device | **N/A** |
| **5.2.4** | **Splash resistance** | | **P** |
| | When tested in accordance with ISO 22609:2004 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1. | See appended table 5.2.4 | **P** |
| **5.2.5** | **Microbial cleanliness (Bioburden)** | | **P** |
| | When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ⩽ 30 CFU/g tested (see Table 1). | See appended table 5.2.5 | **P** |
| **5.2.6** | **Biocompatibility** | | **P** |
| | According to the definition and classification in EN ISO 10993-1:2009, a medical face mask is a surface device with limited contact. | In Vitro Cytotoxicity Test, test report No.: SDWH-M201700783-1, Skin Sensitization Test, test report No.: SDWH-M201700783-2, Skin Irritation Test, test report No.: SDWH-M201700783-3, issued by Sanitation & Environment Technology Institute, Soochow University. | **P** |
| | The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1:2009 and determine the applicable toxicology testing regime. | | **P** |
| | The results of testing should be documented according to the applicable parts of the EN ISO 10993 series. | | **P** |
| | The test results shall be available upon request. | | **P** |
| **6** | **Marking, labelling and packaging** | | **P** |

| EN 14683:2019+AC:2019 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied. | Checked and complied | **P** |
| | The following information shall be supplied: | | **P** |
| | a) number of this European Standard; | Marked on the label | **P** |
| | b) type of mask (as indicated in Table 1). | Marked on the label | **P** |
| | EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered. | Considered | **P** |

| EN 14683:2019+AC:2019 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

| 5.2.2 | TABLE: Bacterial filtration efficiency (BFE) | | | | | | | | P |
|---|---|---|---|---|---|---|---|---|---|
| **Batch/ lot no.:** | **Test Speci -men no.:** | **Dimension of the test specimen L x W (mm x mm)** | **test area (cm²)** | **Flow rate (l/min)** | **The plate counts of the positive control** | **The plate counts of the test specimen** | **Mean plate count of the negative controls** | **BFE for each test specimen (%)** | **Remarks** |
| 200307 | 1 | 156x155 | 63.6 | 28.3 | 2581 | 12 | 0 | 99.54% | P |
| | 2 | 156x155 | 63.6 | 28.3 | 2220 | 14 | | 99.37% | P |
| | 3 | 155x155 | 63.6 | 28.3 | 2512 | 16 | | 99.36% | P |
| | 4 | 158x154 | 63.6 | 28.3 | 2224 | 15 | | 99.33% | P |
| | 5 | 155x155 | 63.6 | 28.3 | 2405 | 24 | | 99.00% | P |

**Supplementary information:**
1, Each specimen was conditioned at 21 °C and 85 % relative humidity for 4 h to bring them into equilibrium with atmosphere prior to testing.
2, The side of the test specimen was facing towards the challenge aerosol: out side of mask

| 5.2.3 | TABLE: Breathability (Differential pressure) | | | | P |
|---|---|---|---|---|---|
| **Batch/ lot no.:** | **Test Specimen number-Test area number** | **Differential pressure for each test area (Pa/cm²)** | **The averaged differential pressure for each test specimen (Pa/cm²)** | **Flow rate (l/min)** | **Remarks** |
| 200307 | 1-1 | 19.6 | 20.7 | 8.0 | P |
| | 1-2 | 23.0 | | 8.0 | P |
| | 1-3 | 19.7 | | 8.0 | P |
| | 1-4 | 23.1 | | 8.0 | P |
| | 1-5 | 17.9 | | 8.0 | P |
| | 2-1 | 17.9 | 21.9 | 8.0 | P |
| | 2-2 | 19.6 | | 8.0 | P |
| | 2-3 | 26.7 | | 8.0 | P |
| | 2-4 | 20.0 | | 8.0 | P |
| | 2-5 | 25.3 | | 8.0 | P |
| | 3-1 | 20.2 | 21.7 | 8.0 | P |
| | 3-2 | 21.1 | | 8.0 | P |

| EN 14683:2019+AC:2019 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

| | | | | | |
|---|---|---|---|---|---|
| | 3-3 | 21.5 | | 8.0 | P |
| | 3-4 | 21.7 | | 8.0 | P |
| | 3-5 | 23.8 | | 8.0 | P |
| | 4-1 | 24.1 | 23.0 | 8.0 | P |
| | 4-2 | 25.1 | | 8.0 | P |
| | 4-3 | 21.0 | | 8.0 | P |
| | 4-4 | 22.4 | | 8.0 | P |
| | 4-5 | 22.3 | | 8.0 | P |
| | 5-1 | 20.4 | 21.8 | 8.0 | P |
| | 5-2 | 20.0 | | 8.0 | P |
| | 5-3 | 22.6 | | 8.0 | P |
| | 5-4 | 19.2 | | 8.0 | P |
| | 5-5 | 27.0 | | 8.0 | P |

**Supplementary information:**

Each specimen was conditioned at 21 °C and 85 % relative humidity for 4 h to bring them into equilibrium with atmosphere prior to testing.

| 5.2.4 | TABLE: Splash resistance | | | P |
|---|---|---|---|---|
| **Batch/ lot no.:** | **Test mask no.:** | **The material of tested mask** | **Test result (Pass/fail)** | **Remarks** |
| **200307** | **1** | **Polypropylene fused jet filter layer** | **Pass** | |
| | **2** | **Polypropylene fused jet filter layer** | **Pass** | |
| | **3** | **Polypropylene fused jet filter layer** | **Pass** | |
| | **4** | **Polypropylene fused jet filter layer** | **Pass** | |
| | **5** | **Polypropylene fused jet filter layer** | **Pass** | |
| | **6** | **Polypropylene fused jet filter layer** | **Pass** | |
| | **7** | **Polypropylene fused jet filter layer** | **Pass** | |
| | **8** | **Polypropylene fused jet filter layer** | **Pass** | |

| EN 14683:2019+AC:2019 | | | | |
|---|---|---|---|---|
| Clause | Requirement + Test | | Result - Remark | Verdict |
| | 9 | Polypropylene fused jet filter layer | Pass | |
| | 10 | Polypropylene fused jet filter layer | Pass | |
| | 11 | Polypropylene fused jet filter layer | Pass | |
| | 12 | Polypropylene fused jet filter layer | Pass | |
| | 13 | Polypropylene fused jet filter layer | Pass | |
| | 14 | Polypropylene fused jet filter layer | Pass | |
| | 15 | Polypropylene fused jet filter layer | Pass | |
| | 16 | Polypropylene fused jet filter layer | Pass | |
| | 17 | Polypropylene fused jet filter layer | Pass | |
| | 18 | Polypropylene fused jet filter layer | Pass | |
| | 19 | Polypropylene fused jet filter layer | Pass | |
| | 20 | Polypropylene fused jet filter layer | Pass | |
| | 21 | Polypropylene fused jet filter layer | Pass | |
| | 22 | Polypropylene fused jet filter layer | Pass | |
| | 23 | Polypropylene fused jet filter layer | Pass | |
| | 24 | Polypropylene fused jet filter layer | Pass | |
| | 25 | Polypropylene fused jet filter layer | Pass | |
| | 26 | Polypropylene fused jet filter layer | Pass | |
| | 27 | Polypropylene fused jet filter layer | Pass | |
| | 28 | Polypropylene fused jet filter layer | Pass | |
| | 29 | Polypropylene fused jet | Pass | |

| EN 14683:2019+AC:2019 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

| | | | | |
|---|---|---|---|---|
| | | **filter layer** | | |
| | **30** | **Polypropylene fused jet filter layer** | **Pass** | |
| | **31** | **Polypropylene fused jet filter layer** | **Pass** | |
| | **32** | **Polypropylene fused jet filter layer** | **Pass** | |

**Supplementary information:**

1, Each specimen was conditioned at 21 °C and 85 % relative humidity for 4 h to bring them into equilibrium with atmosphere prior to testing.
2, The description of target area tested: the centre of the specimen
3, Any technique used to enhance visual detection of synthetic blood: cotton absorbent swab
4, The temperature and relative humidity for testing: 21 °C and 80 %
5, Description of any pre-treatment techniques used: N/A

| **5.2.5** | **TABLE: Microbial cleanliness (Bioburden)** | | | **P** |
|---|---|---|---|---|
| **Batch/ lot no.:** | **Mask(under test) no.:** | **Weight of each mask (g)** | **Total bioburden per individual mask (CFU/g)** | **Remarks** |
| **200307** | **1** | **2.9** | **＜1** | **P** |
| | **2** | **2.8** | **＜1** | **P** |
| | **3** | **2.8** | **18** | **P** |
| | **4** | **2.9** | **＜1** | **P** |
| | **5** | **2.9** | **＜1** | **P** |

**Supplementary information:**

**End of test report**

# EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Manufacturer:
Name: Hangzhou Yoniner Pharmaceutical Co., Ltd.
Add: Nanyang Economic Development Zone, Xiaoshan, Hangzhou, Zhejiang, China

European Representative:
Company：Lotus NL B.V.
Address：Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
E-mail：peter@lotusnl.com
Tel：+31644168999

Product Name: **Medical** Face Mask
Classification and relevant Rule of MDR: I
（MDR MDREU-2017-745 Annex VIII Cleassification rules Rule 4）

Types/Models: **Type I (BFE95%) ;Type II(BFE98%) ;Type IIR(BFE98%)**
The UMDNS code:CIBG-20200693
Product Certification Conformity Assessment Route:
**EN 14683：2019 Medical face masks - Requirements and test methods**

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All technical documentations are retained under the promise of the manufacturer.

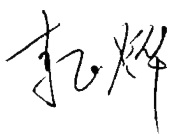
## Laws and regulations

Medical Laws and regulations: MDREU-2017-745

**Benannte Stelle: /**
**Notified Body: /**
**Organisme notifié: /**
**Organismo notificato:**

**TÜV Rheinland LGA Products GmbH**
**Tillystraße 2**
**90431 Nürnberg**
**Deutschland**
**CE 0197**

**Signature of issue person:**
**Position: General Manager**
**Date: 2020.03.13**



# European Authorized Representation Agreement

No.2424#

**Party A**:

Company Name: Hangzhou Yoniner Pharmaceutical Co.,Ltd.

Company Address: Nanyang Economic Development Zone,Xiaoshan,Hangzhou,China. 311227

Tel：+0086-571-82172372 Fax：+0086-571-82171268

**Party B**:

Company Name : **Lotus NL B.V.**

Company Address：Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Tel：+31644168999 Email：peter@lotusnl.com

Party A hereby appoints party B as the Authorized Representative within the European Union,Turkey and Switzerland, and party B accepts the appointment to be the Authorized Representative within the forsaid area for party A. Both parties enter this agreement as follow:

**Party A**

1. Party A assures to provide the updated technical files of each category products bearing the CE marking to party B.

2. If there are any changes of products, party A shall notify party B at once.

3. Party A shall keep records of serial numbers or production lot numbers for all Products delivered to Party B. Records shall include the following information :
   a)name and address of the customer,
   b)product name and specification,
   c)quantity dispatched,
   d)date transferred to the customer,
   e)serial or production lot numbers.
   It is agreed that these records shall be available for inspection upon request by party B or by the relevant authorities.
4. If any serious accident of products occurs within the member states of the European Union, party A shall help party B to investigate the reason in time, and complete the initial report together

with party B. Party A shall present the investigation result and final report to party B within the time limit stipulated by EU laws and/or regulations. If the accident of the product occurs outside the member states of the European Union, party A shall notify party B as soon as possible, and make decision whether to report to competent authority or not.

5. Party A shall be responsible for any business dispute such as claim for compensation caused by medical accident after sale, party B may handle the dispute in accordance with the authorization of party A. All the expenses which should be confirmed by party A occurred during the party B's handling of the accident shall be borne by party A.

6. Party A shall be responsible for the content of instruction(user's) manuals, and shall ensure that English language instruction manuals are available to Party B. Party A shall ensure that the required local language instruction manuals are provided to the customers.

**Party B:**

1. Party B shall be responsible to record all customer and market claims related to the products of Party A and transfer the information to Party A upon receiving of such claims.

2. Party B shall notify Part A about any claims of customers, and change of laws and regulations related to Part A's products bearing CE marking.

3. If any serious accident of products happen within boundary of EU, party B shall notify party A as soon as possible and assist party A to execute vigilance system of medical device products, and also make initial report, investigation result and final report to competent authority of country in which the accidents occur.

4.Party B shall keep technical files of party A's products bearing the CE marking, and take up the responsibility of confidentiality. The technical files shall be kept at least 10 years（implantable devices 15 years） after manufacturing the product of last batch. Party B should present the technical files timely to any competent authority that, for vigilance purpose, needs to inspect or audit the technical files.

5. Party B shall keep records of the Products delivered to end-users or distributors so that the traceability of sold products can be performed at any time upon request.

**Appendix A**

1. This agreement will be terminated automatically if the CE certification of party A be withdrawn by the notified body during the implementation of the agreement.

2.If party A plans to ship the devices to EU countries and British, party B can support party A to get the devices registered at British according to MHRA and related applicable regulation. This service is not included in this European Authorized Representative Agreement, and party A should inform party B at least 2 months ealier before the shipment and pay the involved registration fee(MDD Class I,and all IVDD Products ).

3. 3.Validity term of agreement is signed by European Authorized Representative.
（有效期：**25/FEB/2019-15/JUN/2025**）

4. The following countries represent party B's Business Area :
European Union（E.U.）,EEA and Switzerland,Turkey.

5. For the following Product Categories :
Wound bandages(I*), Plasters(I), Wound plasters(I*),
Wound dressings(IIa),
Gauze(IIa) , Sterile gauzes(IIa),
Sterile bandages(I*), Sterile first aid bandages(I*)
Medical tapes(I)(sports tapes,non-woven tapes,paper tapes,elastic tapes,waterproof tapes,PE tapes,silk tapes)
Zinc Oxide plasters(I)
First Aid Kits(I)
Bandages(I), Cohesive bandage(I), First aid kits(I)
Disposal Surgical Masks

**Party A**

**Hangzhou Yoniner Pharmaceutical Co.,Ltd.**

Signature:

Date:

Place:

**Party B**

**Lotus NL B.V.**

Signature:

Date: **25/MAR/2020**

Place: **Hague**

180011112242

（2018）国认监认字（244）号

中国认可
国际互认
检测
TESTING
CNAS L6780

# 检 验 报 告

# TEST REPORT

扫一扫关注我们　　扫一扫查询真伪

报 告 编 号
REPORT NO.　国纺委字第 YJ202002724 号

产 品 名 称
NAME OF SAMPLE　一次性口罩

委 托 单 位
CUSTOMER　杭州江南世家药业有限公司

检 验 类 别
TEST CATEGORY　委托检验


**浙江省轻工业品质量检验研究院**

**（浙江省纺织测试研究院）**

**Zhejiang Light Industrial Products Inspection and Research Institute**

**国家纺织服装产品质量监督检验中心（浙江）**

**National Textiles and Garment Quality Supervision Inspection Center(Zhejiang)**

浙江省轻工业品质量检验研究院
国家纺织服装产品质量监督检验中心（浙江）

# 检验报告

国纺委字第 YJ202002724 号　　第 1 页 共 3 页

| | | | |
|---|---|---|---|
| 委托单位名称 Name of Customer | 杭州江南世家药业有限公司 | 地 址 Address | 杭州市萧山区南阳经济开发区阳城路 42 号 |
| 生产单位 Manufacturer | --- | 地 址 Address | --- |
| 样品信息 Sample information | 样品名称 Name of sample：一次性口罩<br>样品特性 Characteristics：蓝色<br>商标 Trademark：---<br>规格/号型 Specification/model：175*95mm<br>等 级 Level：---<br>安全技术类别 Category of safety specification：---<br>样品款号/货号 Art. No.：20200307<br>---------- | | |
| 以上为客供信息（Above-mentioned information by Customer-supplied） | | | |
| 来样方式 The sent way of sample | 自送 | 样品数量 Sample quantity | 1 包 |
| 送检日期 Receiving Date of Sample | 2020-03-12 | 检测类别 Test Category | 委托检验 |
| 判定依据 RatingRequirements | GB/T 32610-2016 | | |

检测结论/Test Summary：

实测结果详见附页。

（检验报告专用章）Test Seal

批准日期/ Date of Approval：2020-03-13

| | |
|---|---|
| 备 注 Remarks | 1、样品标识未标注防护效果级别，按最低标准要求 D 级判定。<br>2、样品未经预处理。<br>3、生产日期：2020-03-07。 |

签 发：
Approved by

# 检验报告

国纺委字第 YJ202002724 号

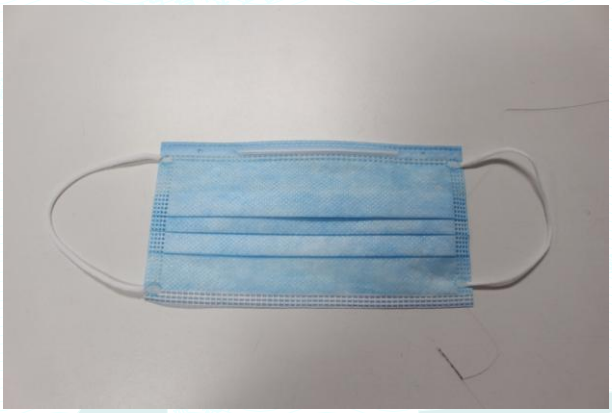


| 序号 | 检测项目 | | 检测方法 | 单位 | 标准要求（D 级） | 实测值 | 单项评价 | 结果备注 |
|---|---|---|---|---|---|---|---|---|
| 1 | 呼吸阻力 | 吸气阻力 | GB/T 32610-2016 | Pa | ≤175 | 47.3 | 符合 | --- |
| | | 呼气阻力 | | Pa | ≤145 | 43.6 | | |
| 2 | 过滤效率（盐性介质） | | GB/T 32610-2016 附录 A | % | ≥90 | 95.1 | 符合 | --- |
| 3 | 防护效果 | | GB/T 32610-2016 附录 B | % | ≥65 | 70.0 | 符合 | --- |

# 检验报告



样品照片



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# 声明

一、本机构保证检测的公正性、独立性和诚实性，对检测结果负责，对委托方所提供的检测样品保密和保护所有权。
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# DECLARATION

1. Our organization guarantees impartiality, independence and honesty of inspection, and is responsible for the results of inspection, keeping the samples supplied by the entrusting party confidential and at the same time protecting the ownership of the samples supplied.
2. The test report will be deemed invalid without signatures of the inspector/reviewer and authorized personnel, and the red special inspection stamp of our organization.
3. The test report will be invalid if it is altered. Copies of the report are invalid without the red special inspection stamp of our organization.
4. The test results shown in this report is only valid for the tested sample.
5. All the pages of the report are integral parts of the report. Our organization will not be responsible for any misunderstanding or other results caused by using separate page(s) of the report.
6. If there is any dissent of the report, the entrusting party shall notify our organization timely. For the mandatory inspection given by governmental administration departments, and dissent about the sample being tested or test results on the report should be dealt with in accordance with national regulations.

## 浙江省轻工业品质量检验研究院及附设的检验中心
## The Affiliated Inspection Centers


浙江省轻工业品质量检验研究院　　联系电话：0571-85122669
Zhejiang Light Industrial Products InspectionandResearchInstitute　　Telephone：0571-85122669
国家纺织服装产品质量监督检验中心（浙江）
National Textiles and Garment Quality Supervision Inspection Center(Zhejiang)　　E-Mail：1137907994@qq.com
地址：浙江省杭州市江干区下沙路 300 号 6 号楼
Address：Building No.6, 300 XiaSha Road, Hangzhou, Zhejiang

国家家具产品质量监督检验中心（浙江）　　联系电话：0571-89009556
National Center for Quality Supervision Inspection of Furniture(Zhejiang)　　Telephone：0571-89009556
浙江省室内安全及家具产品质量检验中心
Zhejiang Center of Quality Test for Indoor Safety and Furniture Products　　E-Mail：2047699564@qq.com
地址：浙江省杭州市余杭区良渚街道经一路 1 号良渚大学科技园 4 号楼
Address：Building 4 LiangZhu University Science and Technology Park, No.1,
JingYi Rd, Yuhang District, Hangzhou, Zhejiang

浙江省轻工及五金产品质量检验中心　　联系电话：0571-89001107
Zhejiang Center of Quality Test for Light Industry and Hardware Products　　Telephone：0571-89001107
浙江省体育用品质量检验中心
Zhejiang Center of Quality Test for Sports Products　　E-Mail：wujtest@126.com
地址：浙江省杭州市西湖区天目山路 222 号 3 号楼
浙江省杭州市余杭区良渚街道经一路 1 号良渚大学科技园 3 号楼
Address：No. 222 Tianmushan Rd., Hangzhou, Zhejiang
Building 3 LiangZhu University Science and Technology Park, No.1,
JingYi Rd., Hangzhou, Zhejiang

国家锁具产品质量监督检验中心（浙江）　　联系电话：0571-85027738
National Center for Quality Supervision Inspection of Lock(Zhejiang)　　Telephone：0571-85027738
浙江省锁具产品质量检验中心
Zhejiang Center of Quality Test for Lock Products　　E-Mail：Locktest@126.com
地址：浙江省杭州市塘苗路 24 号
Address：No. 24 Tangmiao Rd., Hangzhou, Zhejiang

MDST

# 检　验　报　告

## Test Report

报告编号：Z20200915

产 品 名 称：一次性使用医用口罩

规 格 型 号：175×95mm　耳挂式

受 检 单 位：杭州江南世家药业有限公司

检 验 类 别：委托检验

浙 江 省 医 疗 器 械 检 验 研 究 院

ZHEJIANG INSTITUTE OF MEDICAL DEVICE SUPERVISION AND TESTING

浙江省医疗器械检验研究院

# 检 验 报 告

报告编号：Z20200915　　共 6 页 第 1 页

| | | | |
|---|---|---|---|
| 样品名称 | 一次性使用医用口罩 | | |
| 规格型号 | 175×95mm　耳挂式 | 检验类别 | 委托检验 |
| 委托人/单位 | 杭州江南世家药业有限公司 | | |
| 受检单位名称 | 杭州江南世家药业有限公司 | | |
| 制造单位名称 | 杭州江南世家药业有限公司 | | |
| 取样方式 | 送样 | 抽样地点 | / |
| 抽样日期 | / | 抽样基数 | / |
| 抽样人 | / | 样品接受日期 | 2020-03-20 |
| 样品数量 | 12包（10片/包） | 样品生产日期 | 2020.03.15 |
| 样品批号/编号 | / | | |
| 检验依据 | YY/T 0969-2013 | | |
| 检验项目 | 4.1外观、4.2结构与尺寸、4.3鼻夹、4.4口罩带、4.5细菌过滤效率（BFE）、4.6通气阻力、4.7.1微生物指标 | | |
| 检验日期 | 2020年03月20日～2020年04月08日 | | |
| 检验结论 | 被检样品所检项目符合YY/T 0969-2013《一次性使用医用口罩》的要求。<br>检验报告专用章 | | |

批准：张莉　　审核：　　主检：王飘萍

职务：授权签字人

日期：2020.04.09　　日期：2020.04.09　　日期：2020.04.09

# 检 验 报 告



<table>
<tr><td>检验地点</td><td colspan="3">省院、宁波实验室</td><td>本报告共有3幅照片</td></tr>
<tr><td>分包检验项目</td><td colspan="4">/</td></tr>
<tr><td rowspan="2">委托人/单位资料</td><td>电话</td><td>0571-82171118</td><td>邮政编码</td><td>/</td></tr>
<tr><td>地址</td><td colspan="3">杭州市萧山区南阳经济开发区阳城路42号</td></tr>
<tr><td>采用的检验方法</td><td colspan="4">■标准方法；<br>□客户定制的方法；<br>□本实验室提供的方法；<br>□其他方法；</td></tr>
<tr><td>评估测量不确定度的声明/信息</td><td colspan="4">/</td></tr>
<tr><td>意见和解释</td><td colspan="4">/</td></tr>
<tr><td>样品描述</td><td colspan="4">样品状态描述：<br>a) 结构组成:/；<br>b) 原理、用途:/；<br>c) 主要特征参数:外观、结构与尺寸、鼻夹、口罩带、细菌过滤效率、通气阻力、微生物限度；<br>d) 样品状态:完好。</td></tr>
<tr><td>其他说明</td><td colspan="4">/</td></tr>
</table>

# 检 测 结 果 汇 总

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| 序号 | 检测项目 | 标准条款 | 标准要求 | | 实测结果 | | | 判定结论 |
|---|---|---|---|---|---|---|---|---|
| 1 | 外观 | 4.1 | 口罩外观应整洁、形状完好，表面不得有破损、污渍 | | 符合 | | | 合格 |
| 2 | 结构与尺寸 | 4.2 | 口罩佩戴好后，应能罩住佩戴者的口、鼻至下颌 | | 符合 | | | 合格 |
| | | | 应符合设计的尺寸，最大偏差不超过：±5% | 口罩长度：175mm | 1 | 2 | 3 | 合格 |
| | | | | | 171 | 172 | 172 | |
| | | | | 口罩宽度：95mm | 1 | 2 | 3 | 合格 |
| | | | | | 95 | 95 | 95 | |
| 3 | 鼻夹 | 4.3.1 | 口罩上应配有鼻夹，鼻夹由可塑性材料制成 | | 符合 | | | 合格 |
| | | 4.3.2 | 鼻夹长度应不小于8.0cm | | 1 | 2 | 3 | 合格 |
| | | | | | 9.3 | 9.1 | 9.1 | |
| 4 | 口罩带 | 4.4.1 | 口罩带应戴取方便 | | 符合 | | | 合格 |
| | | 4.4.2 | 每根口罩带与口罩体连接点处的断裂强力应不小于10N | | 符合 | | | 合格 |
| 5 | 细菌过滤效率（BFE） | 4.5 | 口罩的细菌过滤效率应不小于95% | | 1 | 2 | 3 | 合格 |
| | | | | | 99.8% | 99.6% | 99.8% | |
| 6 | 通气阻力 | 4.6 | 口罩两侧面进行气体交换的通气阻力应不大于49Pa/$cm^2$ | | 1 | 2 | 3 | 合格 |
| | | | | | 26 | 22 | 23 | |
| 7 | 微生物限度 | 4.7.1 | 细菌菌落总数：≤100CFU/g | | ＜20CFU/g | | | 合格 |
| | | | 大肠菌群：不得检出 | | 未检出 | | | 合格 |

# 检 测 结 果 汇 总



| 序号 | 检测项目 | 标准条款 | 标准要求 | 实测结果 | 判定结论 |
|---|---|---|---|---|---|
| | | | 绿脓杆菌：不得检出 | 未检出 | 合格 |
| | | | 金黄色葡萄球菌：不得检出 | 未检出 | 合格 |
| | | | 溶血性链球菌：不得检出 | 未检出 | 合格 |
| | | | 真菌：不得检出 | 未检出 | 合格 |

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# EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Manufacturer:
Name: Hangzhou Yoniner Pharmaceutical Co., Ltd.
Add: Nanyang Economic Development Zone, Xiaoshan, Hangzhou, Zhejiang, China

European Representative:
Company：Lotus NL B.V.
Address：Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
E-mail：peter@lotusnl.com
Tel：+31644168999

Product Name: **Medical** Face Mask

Classification (MDD, Annex IX): Class I Non Sterile Rule Conformity Assessment Route: Annex VII

Types/Models: **Type I (BFE95%) ;Type II(BFE98%) ;Type IIR(BFE98%)**
The UMDNS code:CIBG-20200693

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All technical documentations are retained under the promise of the manufacturer.

## Laws and regulations

General applicable directives:Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC Harmonized Standards: EN 14683:2019+AC:2019

**Benannte Stelle: /**
**Notified Body: /**
**Organisme notifié: /**
**Organismo notificato:**

**TÜV Rheinland LGA Products GmbH**
**Tillystraße 2**
**90431 Nürnberg**
**Deutschland**

**Signature of issue person:**
**Position: General Manager**
**Date: 2020.03.13**