

# CE DECLARATION OF CONFORMITY

Name and address of the manufacturer: /

**G.R.M.E. CO.,LTD**  
Yin Sha Industrial Park,  
Zengcheng District, Guangzhou

EC Authorized Representative: /

**Shanghai International Holding Corp. GmbH (Europe)**  
Eiffestrasse 80, 20537 Hamburg, Germany

**We declare under our sole responsibility that:**

Name of the medical device: /

**Disposable Medical Mask (Non-sterile)**

Type: /

**Type IIR**

Product code: /

**UMDNS code 12447(Masks,Medical)**

Intended purpose: /

**The Disposable medical mask is intended to be worn to protect against the spread or transmission of infectious germs in a general medical facility. The main aim is to protect the patient against infectious germs. In addition, in certain situations the wearer should be protected against splashes of potentially contaminated liquids and viable particles.**

Basic UDI-DI: /

**NA**

Trade name: /

**None**

Of class: /

**Rule1, Class I**  
according to annex IX of Regulation(EU)93/42/EEC

CS reference: /

**NONE**

Applicable standards: /

**EN 14683:2019+AC:2019**  
**EN ISO 10993-5:2009**  
**EN ISO 10993-10:2013**

Conformity assessment: /

**We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC and 2007/47/EC for medical devices as transposed into national law. All supporting documentation is retained under the premises of the manufacturer.**



*Guangzhou P.R. April 20th 2020*

Ort, Datum / Place, date /  
Lieu, date / Luogo, data

Name und Funktion / Name and function /  
Nom et fonction / Nome e funzione



*Jiangda Song, Manager*



## Test Report

No.: GZHL2003008064MD-02

Date: May 12, 2020

Page 1 of 8

G. R. M. E. CO., LTD.  
YIN SHA INDUSTRIAL PARK,  
ZENGCHENG DISTRICT, GUANGZHOU

Sample Description : KOJINSI DISPOSABLE MEDICAL MASK ( NON-STERILE)  
Style / Item No. : EARLOOP  
Lot No. : 130501  
Size : 17.5cm X 9.5cm  
Classification : TYPE IIR  
Country of Destination : EU

As above test item and its relevant information regarding to the submission are provided and confirmed by the applicant. SGS is not liable to either the test item or its relevant information, in terms of the accuracy, suitability, reliability or/and integrity accordingly.

\*\*\*\*\*

Sample Receiving Date : Mar 27, 2020  
Test Performing Date : Mar 27, 2020 to Apr 15, 2020  
Test Performed : Selected test(s) as requested by applicant  
Test Result(s) :

Test Requested	Result
EN 14683:2019+AC:2019 excluding clause 6	Pass

Signed for and on behalf of  
SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch



Arthur Mak  
Authorized Signatory



SGS-CSTC Standards Technical Services Co., Ltd.  
Guangzhou Branch Testing Center Harlines

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Member of the SGS Group (SGS SA)



**Test Conducted: EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods**
**Scope**

This document specifies construction, design, performance requirements and test methods for medical face masks intended to limit the transmission of infective agents from staff to patients during surgical procedures and other medical settings with similar requirements. A medical face mask with an appropriate microbial barrier can also be effective in reducing the emission of infective agents from the nose and mouth of an asymptomatic carrier or a patient with clinical symptoms.

**1. Sample description:**

<b>Classification</b>	<input type="checkbox"/> Type I <input type="checkbox"/> Type II <input checked="" type="checkbox"/> Type IIR (For type II, The 'R' signifies splash resistance)
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**2. Test Results:** Details shown as following table

Clause	Test Item	Test Requirement / Test Method	Test Result
<b>5 Requirement</b>			
5.1	General	---	---
5.1.1	Materials and construction	The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric. The medical face mask shall not disintegrate, split or tear during intended use. In the selection of the filter and layer materials, attention shall be paid to cleanliness.	PASS See Table 1
5.1.2	Design	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.  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).	PASS See Table 2
<b>5.2 Performance requirements</b>			
5.2.1	General	All tests shall be carried out on finished products or samples cut from finished products.	PASS See Table 3



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Guangzhou Branch Testing Center

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Clause	Test Item	Test Requirement / Test Method	Test Result
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.</p> <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.</p> <p>When a mask consists of two or more areas with different characteristics or different layer composition, each panel or area shall be tested individually. The lowest performing panel or area shall determine the BFE value of the complete mask.</p>	PASS See Table 4
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.</p> <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).</p>	PASS See Table 5
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.</p>	PASS See Table 6
5.2.5	Microbial cleanliness (Bioburden)	<p>When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be <math>\leq 30</math> CFU/g tested (see Table 1).</p> <p>NOTE EN ISO 11737-1:2018 specifies requirements and provides guidance for the enumeration and microbial characterization of the population of viable microorganisms on or in a medical device, component, raw material or package.</p> <p>To determine the mask's bioburden according to EN ISO 11737-1:2018, refer to the procedure as described in Annex D.</p> <p>The number of masks that shall be tested is minimum 5 of the same batch/lot.</p> <p>Other test conditions as described in EN ISO 11737-1:2018 may be applied.</p>	PASS See Table 7



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Clause	Test Item	Test Requirement / Test Method	Test Result																				
		In the test report, indicate the total bioburden per individual mask and based on the mask weight, the total bioburden per gram.																					
5.2.6	Biocompatibility	According to the definition and classification in EN ISO 10993-1:2009, a medical face mask is a surface device with limited contact. 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. The results of testing should be documented according to the applicable parts of the EN ISO 10993 series. The test results shall be available upon request.	PASS																				
5.2.7	Summary of performance requirements	<p><b>Table 1 — Performance requirements for medical face masks</b></p> <table> <tr> <th>Test</th><th>Type I<sup>a</sup></th><th>Type II</th><th>Type IIR</th></tr> <tr> <td>Bacterial filtration efficiency (BFE), (%)</td><td>≥ 95</td><td>≥ 98</td><td>≥ 98</td></tr> <tr> <td>Differential pressure (Pa/cm<sup>2</sup>)</td><td>&lt; 40</td><td>&lt; 40</td><td>&lt; 60</td></tr> <tr> <td>Splash resistance pressure (kPa)</td><td>Not required</td><td>Not required</td><td>≥ 16,0</td></tr> <tr> <td>Microbial cleanliness (cfu/g)</td><td>≤ 30</td><td>≤ 30</td><td>≤ 30</td></tr> </table> <p><sup>a</sup> Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.</p>	Test	Type I <sup>a</sup>	Type II	Type IIR	Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98	Differential pressure (Pa/cm <sup>2</sup> )	< 40	< 40	< 60	Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0	Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30	---
Test	Type I <sup>a</sup>	Type II	Type IIR																				
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98																				
Differential pressure (Pa/cm <sup>2</sup> )	< 40	< 40	< 60																				
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0																				
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30																				
<b>6 Marking, labeling and packaging</b>																							
---	---	<p>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.</p> <p>The following information shall be supplied:</p> <p>a) number of this European Standard;</p> <p>b) type of mask (as indicated in Table 1).</p> <p>EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.</p>	NT																				

**Remark :**

1. NT-Not test as per client's requirement.
2. Above test was subcontracted to Guangzhou Inspection Testing and Certification Group Co.,Ltd.
3. This test report is to supersede No. GZHL2003008064MD test report which was issued on Apr 15, 2020. And
4. the original test reports (paper and electronic) are invalid.

**Appendix:**
**Table 1**
**Materials and construction:**

Requirement	Conclusion
The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric.	Pass
The medical face mask shall not disintegrate, split or tear during intended use.	Pass
In the selection of the filter and layer materials, attention shall be paid to cleanliness.	Pass

**Table 2**
**Design:**

Requirement	Conclusion
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.	Pass
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).	Pass

**Table 3**
**General:**

Requirement	Conclusion
All tests shall be carried out on finished products or samples cut from finished products.	Pass





**Table 4**
**Bacterial filtration efficiency (BFE):**

Sample	T	BFE (%)	Requirement (%)	Classification	Conclusion
1	11	99.42	$\geq 98$ EN 14683:2019+AC:2019	Type IIR	Pass
2	12	99.37			
3	16	99.16			
4	13	99.32			
5	16	99.16			

For each test specimen calculate the bacterial filtration efficiency B, as a percentage, using the following formula:

$$B = (C - T) / C \times 100$$

Where:

B is bacterial filtration efficiency (BFE), %;

C is positive control average;

T is the total plate count for the test specimen.

**Remark:**

1. Dimension of test specimen(L X W):15cmx15cm;
2. Test area of specimen(cm<sup>2</sup>):40cm<sup>2</sup>;
3. The side of the test specimen was facing towards the challenge aerosol:inside;
4. Flow rate:28.3L/min;
5. Mean of the total plate counts of the two positive controls:1.9x10<sup>3</sup> CFU;
6. Mean plate counts of negative controls:<1 CFU.

**Table 5**
**Breathability:**
**Differential pressure**

Sample	Measured Value(Pa)	Differential pressure (Pa/cm <sup>2</sup> )	Requirement (Pa/cm <sup>2</sup> )	Classification	Conclusion
1	237	45.9	$< 60$ EN 14683:2019+AC:2019	Type IIR	Pass
2	192				
3	234				
4	245				
5	217				
Average	225				

**Remark:**

1. Flow rate during testing:8 L/min;
2. Test area:4.9cm<sup>2</sup>.
3. General location of the areas of the mask the differential measurements were taken:specimen center.



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**Table 6**
**Splash resistance**

Sample	Measured value	Requirement (kPa)	Classification	Conclusion
	Pressure			
	16.0kpa			
1	Pass	≥16 EN 14683:2019+AC:2019	Type IIR	Pass
2	Pass			
3	Pass			
4	Pass			
5	Pass			
6	Pass			
7	Pass			
8	Pass			
9	Pass			
10	Pass			
11	Pass			
12	Pass			
13	Pass			
14	Pass			
15	Pass			
16	Pass			
17	Pass			
18	Pass			
19	Pass			
20	Pass			
21	Pass			
22	Pass			
23	Pass			
24	Pass			
25	Pass			
26	Pass			
27	Pass			
28	Pass			
29	Pass			
30	Pass			
31	Pass			
32	Pass			
Final result	Pass			

**Remark:**

1. An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show "Pass" results;
2. Pretreatment:condition each specimen for 24 h by exposure to a temperature of (21±5)°C and a relative humidity of (85±5)%;
3. Surface tension of synthetic blood:0.042 N/m;
4. Pressure:16.0 kPa;
5. Velocity:550 cm/s;
6. Whether the targeting-plate method was used:Yes.
7. Description of any technique used to enhance visual detection of synthetic blood: /



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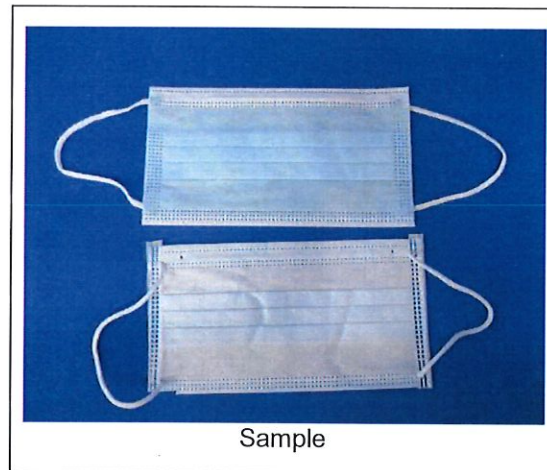
Table 7

Microbial cleanliness (Bioburden):

Sample	Measured Value (CFU/g)	Microbial cleanliness (CFU/g)	Requirement (CFU/g)	Classification	Conclusion
Bacteria	20	26	≤30 EN 14683:2019+AC:2019	Type IIR	Pass
Fungi	6				

Remark: Subcontracted to Guangzhou Inspection Testing and Certification Group Co., Ltd.

Sample Photo(s):



Remark: This test report is to supersede No. GZHL2003008064MD-01 test report which was issued on Apr 20, 2020. And the original test reports (paper and electronic) are invalid.

\*\*\*End of Report\*\*\*



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# **Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG** **General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG**

## **Formblatt für Medizinprodukte, außer In-vitro-Diagnostika** **Form for Medical Devices except In Vitro Diagnostic Medical Devices**

<b>Zuständige Behörde / Competent authority</b>	
Code <b>DE/CA05</b>	
Bezeichnung / Name <b>Behörde für Gesundheit und Verbraucherschutz, Referat V43</b>	
Staat / State <b>Deutschland</b>	Land / Federal state <b>Hamburg</b>
Ort / City <b>Hamburg</b>	Postleitzahl / Postal code <b>20539</b>
Straße, Haus-Nr. / Street, house no. <b>Billstraße 80</b>	

<b>Anzeige / Notification</b>	
Registrierdatum bei der zuständigen Behörde Registration date at competent authority <b>29.04.2020</b>	Registriernummer / Registration number <b>DE/CA05/MP-238321-2585-00</b>
Typ der Anzeige / Notification type <input checked="" type="checkbox"/> Erstanzeige / Initial notification <input type="checkbox"/> Änderungsanzeige / Notification of change <input type="checkbox"/> Widerrufsanzeige / Notification of withdrawal	
Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn	
Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG <input type="checkbox"/> Hersteller / Manufacturer <input checked="" type="checkbox"/> Bevollmächtigter / Authorised Representative <input type="checkbox"/> Einführer / Importer <input type="checkbox"/> Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG <input type="checkbox"/> Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV <input type="checkbox"/> Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG	



<b>Anzeigender / Reporting organisation (person)</b>			
	Code <b>DE/0000040627</b>		
	Bezeichnung / Name <b>Shanghai International Holding Corporation GmbH (Europe)</b>		
	Staat / State <b>Deutschland</b>		Land / Federal state <b>Hamburg</b>
	Ort / City <b>Hamburg</b>		Postleitzahl / Postal code <b>20537</b>
	Straße, Haus-Nr. / Street, house no. <b>Eiffestrasse 80</b>		

<b>Hersteller / Manufacturer</b>			
	Bezeichnung / Name <b>G. R. M. E. Co., Ltd.</b>		
	Staat / State <b>CN</b>		
	Ort / City <b>Guangzhou</b>		Postleitzahl / Postal code <b>12345</b>
	Straße, Haus-Nr. / Street, house no. <b>Yin Sha Industrial Park, Zengcheng District</b>		

<b>Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9)</b> <b>Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG</b>			
	Bezeichnung / Name <b>Liang Jin</b>		
	Staat / State <b>Deutschland</b>		Land / Federal state <b>Hamburg</b>
	Ort / City <b>Hamburg</b>		Postleitzahl / Postal code <b>20537</b>
	Straße, Haus-Nr. / Street, house no. <b>Eiffestr.80</b>		

<b>Vertreter / Deputy (optional)</b>		
	Bezeichnung / Name	
	Telefon / Phone	Telefax / Fax
	E-Mail / E-mail	
	<input type="checkbox"/> Erstanzeige / Initial notification <input checked="" type="checkbox"/> Änderungsanzeige / Notification of change	



Medizinprodukt (Erstmaliges Inverkehrbringen) / Medical device (First placing on the market)	
	<p>Klasse / Class</p> <p><input checked="" type="checkbox"/> I</p> <p><input type="checkbox"/> I - steril / sterile</p> <p><input type="checkbox"/> I - mit Messfunktion / with measuring function</p> <p><input type="checkbox"/> I - steril und mit Messfunktion / sterile and with measuring function</p> <p><input type="checkbox"/> IIa</p> <p><input type="checkbox"/> IIb</p> <p><input type="checkbox"/> III</p> <p><input type="checkbox"/> III - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012</p> <p><input type="checkbox"/> Aktives implantierbares Medizinprodukt / Active implantable medical device</p> <p><input type="checkbox"/> Aktives implantierbares Medizinprodukt - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 Active implantable medical device - manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012</p>
	<p>App (Software auf mobilen Endgeräten) <span style="float: right;"><input type="checkbox"/> ja / yes <input checked="" type="checkbox"/> nein / no</span></p>
	Nummer(n) der Bescheinigung(en) / Certificate number(s)
	Handelsname des Produktes / Trade name of the device <b>Ruisen</b>
	Produktbezeichnung / Name of device <b>Disposable medical mask</b>
	Nomenklaturcode / Nomenclature code <b>12-447</b>
	Nomenklaturbezeichnung / Nomenclature term <b>Maske</b>
	Kategoriecode / Category code <b>10</b>
	Kategorie / Category <b>Produkte zum Einmalgebrauch</b>
	Kurzbeschreibung deutsch / German short description
	Kurzbeschreibung englisch / English short description <b>Disposable medical mask is intended to cover the user's mouth and nose, to be worn in a general medical environment, to block the mouth and nasal cavity from exhaling or spraying pollutants.</b>

Medizinprodukte (Aufbereiten) / Medical devices (Reprocessing)	
<input type="checkbox"/>	Semikritische Medizinprodukte / Semicritical medical devices <input type="checkbox"/> Gruppe A / Group A <input type="checkbox"/> Gruppe B / Group B
<input type="checkbox"/>	Kritische Medizinprodukte / Critical medical devices <input type="checkbox"/> Gruppe A / Group A <input type="checkbox"/> Gruppe B / Group B <input type="checkbox"/> Gruppe C / Group C Nummer der Bescheinigung / Certificate number
<input type="checkbox"/>	Sterilisationsverfahren / Sterilisation procedures <input type="checkbox"/> Dampfsterilisation / Steam sterilisation <input type="checkbox"/> Gassterilisation / Gas sterilisation <input type="checkbox"/> Strahlensterilisation / Radiation sterilisation <input type="checkbox"/> andere / others Angewandtes Verfahren / Applied procedure

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.  
I affirm that the information given above is correct to the best of my knowledge.

Ort  
City Hamburg

Datum  
Date 2020-03-27

Name Liang Jin

Unterschrift  
Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority	
Bearbeiter / Person responsible <b>Frau Bianca Tiemann</b>	Telefon / Phone <b>040-42837 2008</b>



15mm

105mm

95mm

72mm

15mm

200mm

105mm

200mm

105mm



MASCARILLA QUIRÚRGICA IIR DESECHABLE

DISPOSABLE MEDICAL MASK **IIR**



50 pcs



Disposable Medical Mask **IIR**



C/ Sofia, 3-5 - Pol. Ind. Cabezo Beaza  
30353 Cartagena (Spain)

Guangzhou Ruisen Medical Equipment Co., LTD  
4/F, Building B1, No. 1 Zhongshan Road, Yin Sha  
Industrial Park, Sha Pu, Xuzhang Town, Zengcheng  
District, Guangzhou

SC REP  
Shanghai International Holding  
Corp. GmbH (Europe)  
Erftstrasse 80, 20537 Hamburg,  
Germany



LOT 20200728A

28.07.2020

2021/07

**Precauciones:**

- a. Solamente para un único uso. La reutilización del dispositivo puede causar infección cruzada o protección insuficiente.
- b. No lo reutilice después de secar o desinfectar.
- c. Distinga correctamente la parte delantera y trasera antes de usar.
- d. Por favor, preste atención a la fecha de vencimiento del producto antes de su uso
- e. Deseche adecuadamente las mascarillas usadas de acuerdo con la política local de eliminación de desechos médicos.
- f. El dispositivo no debe usarse durante más de 24 horas
- g. Manténgalo alejado del fuego.
- h. No usar si es alérgico a telas no tejidas

Mascarilla médica quirúrgica IIR desechable

INSTRUCCIONES DE USO

1. Lavarse las manos con agua y jabón o frotarlas con una solución hidroalcohólica antes de manipular la mascarilla.
2. Identificar la parte superior de la mascarilla.
3. Colocar la mascarilla en la cara y ajustar la pinza nasal en la nariz.
4. Sostener la mascarilla desde el exterior y pasar el arnés de cabeza o anudarlo detrás de la misma, a ambos lados de las orejas, sin cruzarlos.
5. Bajar la parte inferior de la mascarilla a la barbilla y verificar que la mascarilla cubre la barbilla.
6. Pellicar la pinza nasal con ambas manos para ajustarla a la nariz y verificar que está colocada correctamente.
7. Una vez ajustada, no tocar la mascarilla con las manos.



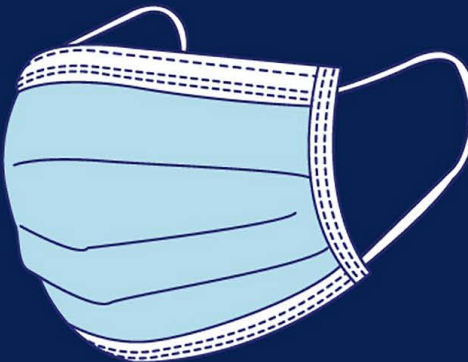
DISPOSABLE MEDICAL MASK **IIR**

Size : 17.5\*9.5cm **BFE≥98%** **Pa/cm2<60**

Type **IIR** according to EN 14683:2019, YY/T0969-2013

Material Composition: 3Ply, Inner layer: PP non-woven (28%)  
Middle layer: meltblown non-woven (34%)  
Outer layer: PP non-woven (38%)  
Medical Device  
Production License: Guangzhou Ruisen Medical Equipment Co., LTD  
Production No. 20200574 (provisional)

MASCARILLA QUIRÚRGICA IIR DESECHABLE



50 pcs/box

USO PREVISTO

Las máscaras faciales **médicas** deben usarse para proteger principalmente contra la propagación o transmisión de gérmenes infecciosos y agentes patógenos. El objetivo principal es proteger al paciente, y una de las características diferenciadoras de la mascarilla IIR es la protección adicional del usuario, que en ciertas situaciones se ve expuesto a salpicaduras de líquidos y microgotas potencialmente contaminantes y partículas viables.

- Protección de fluidos a pacientes y usuarios
- Suave y fácil de respirar
- No fabricado con látex de caucho natural