Test Report

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.

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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

scan to see the report
GZHL2003008064MD-02

Arthur Mak
Authorized Signatory

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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:

Classification	☐Type I ☐Type II ☑Type IIR (For type II, The 'R' signifies splash resistance)

2. Test Results: Details shown as following table

Clause	Test Item	Test Requirement / Test Method	Test Result
5 Requirement			
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
5.2 Performance requirements			
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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Clause	Test Item	Test Requirement / Test Method	Test Result
5.2.2	Bacterial filtration efficiency (BFE)	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. 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. 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.	PASS See Table 4
5.2.3	Breathability	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. 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).	PASS See Table 5
5.2.4	Splash resistance	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.	PASS See Table 6
5.2.5	Microbial cleanliness (Bioburden)	When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ≤ 30 CFU/g tested (see Table 1). 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. To determine the mask's bioburden according to EN ISO 11737-1:2018, refer to the procedure as described in Annex D. The number of masks that shall be tested is minimum 5 of the same batch/lot. Other test conditions as described in EN ISO 11737-1:2018 may be applied.	PASS See Table 7

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	**Table 1 — Performance requirements for medical face masks** Test / Type I [a] / Type II / Type IIR Bacterial filtration efficiency (BFE), (%): ≥ 95 / ≥ 98 / ≥ 98 Differential pressure (Pa/cm^2): < 40 / < 40 / < 60 Splash resistance pressure (kPa): Not required / Not required / ≥ 16,0 Microbial cleanliness (cfu/g): ≤ 30 / ≤ 30 / ≤ 30 [a] 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.	---
6 Marking, labelilng and packaging			
---	---	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. The following information shall be supplied: a) number of this European Standard; b) type of mask (as indicated in Table 1). EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.	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

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Table 4

Bacterial filtration efficiency (BFE):

Sample	T	BFE (%)	Requirement (%)	Classification	Conclusion
1	11	99.42	⩾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 x 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^2):40cm^2;
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:1.9x10^3 CFU;
6. Mean plate counts of negative controls:＜1 CFU.

Table 5

Breathability:
Differential pressure

Sample	Measured Value(Pa)	Differential pressure (Pa/cm^2)	Requirement (Pa/cm^2)	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^2
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 Pressure 16.0kpa	Requirement (kPa)	Classification	Conclusion
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)℃ 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:/

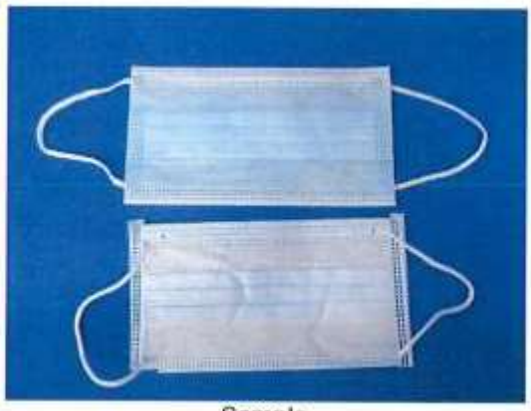
Table 7

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):



Sample

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.

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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

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

Anzeige / Notification			
	Registrierdatum bei der zuständigen Behörde Registration date at competent authority **29.04.2020**		Registriernummer / Registration number **DE/CA05/MP-238321-2585-00**
	Typ der Anzeige / Notification type ☒ Erstanzeige / Initial notification ☐ Änderungsanzeige / Notification of change ☐ 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 ☐ Hersteller / Manufacturer ☒ Bevollmächtigter / Authorised Representative ☐ Einführer / Importer ☐ 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 ☐ 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 ☐ 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		

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

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

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

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Vertreter / Deputy (optional)			
	Bezeichnung / Name		
	Telefon / Phone		Telefax / Fax
	E-Mail / E-mail		
	☐ Erstanzeige / Initial notification ☒ Änderungsanzeige / Notification of change		

Medizinprodukt (Erstmaliges Inverkehrbringen) / Medical device (First placing on the market)	
	Klasse / Class ☒ I ☐ I - steril / sterile ☐ I - mit Messfunktion / with measuring function ☐ I - steril und mit Messfunktion / sterile and with measuring function ☐ IIa ☐ IIb ☐ III ☐ 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 ☐ Aktives implantierbares Medizinprodukt / Active implantable medical device ☐ 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
	App (Software auf mobilen Endgeräten) ☐ ja / yes ☒ nein / no
	Nummer(n) der Bescheinigung(en) / Certificate number(s)
	Handelsname des Produktes / Trade name of the device **Ruisen**
	Produktbezeichnung / Name of device **Disposable medical mask**
	Nomenklaturcode / Nomenclature code **12-447**
	Nomenklaturbezeichnung / Nomenclature term **Maske**
	Kategoriecode / Category code **10**
	Kategorie / Category **Produkte zum Einmalgebrauch**
	Kurzbeschreibung deutsch / German short description
	Kurzbeschreibung englisch / English short description **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.**

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Medizinprodukte (Aufbereiten) / Medical devices (Reprocessing)	
	☐ Semikritische Medizinprodukte / Semicritical medical devices ☐ Gruppe A / Group A ☐ Gruppe B / Group B
	☐ Kritische Medizinprodukte / Critical medical devices ☐ Gruppe A / Group A ☐ Gruppe B / Group B ☐ Gruppe C / Group C Nummer der Bescheinigung / Certificate number
	Sterilisationsverfahren / Sterilisation procedures ☐ Dampfsterilisation / Steam sterilisation ☐ Gassterilisation / Gas sterilisation ☐ Strahlensterilisation / Radiation sterilisation ☐ 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 **Frau Bianca Tiemann**		Telefon / Phone **040-42837 2008**

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