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KF-B P01(R)

MASKA MEDYCZNA

EN 14683:2019 TYPE IIR

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POZOSTAŃ W BEZPIECZEŃSTWIE!

Nasza maska przechodzi rygorystyczne testy i ściśle spełnia wytyczne EN 14683:2019+AC:2019. Przestrzegamy najwyższych standardów jakości, aby zapewnić odpowiednią ochronę.

KINGFA reprezentuje 400 linii produkcyjnych masek o wydajności 40 mln sztuk dziennie.

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Obsługujemy na całym świecie

1 Stany Zjednoczone

2 Niemcy

3 Indie

4 Malezja

5 Chiny

Wewnątrzzakładowa produkcja

Spersonalizowana usługa i całodobowy system śledzenia online

Zwiększenie wydajności

Zarządzanie i kontrola łańcucha dostaw surowców

Krótki czas realizacji

Zagraniczne centra dystrybucji

Kontrola i zarządzanie ryzykiem

Inspekcja i kontrola jakości SGS

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KINGFA uczestniczy w całym łańcuchu branżowym dostaw masek.

Na poziomie niskim

Polimeryzacja polipropylenu

Na poziomie średnim

Materiał Melt Blown

Na ostatnim poziomie

Maski

Kingfa od 27 lat w pełni wykorzystuje swoją zakumulowaną technologię w przemyśle modyfikowanych tworzyw sztucznych. Dzięki doświadczeniu i zaletom kontroli, testowania i certyfikacji przetwarzania polimerów, z powodzeniem opracowaliśmy tkaninę melt-blown o wysokiej wydajności filtracji, która zapewnia niezbędną gwarancję jakości naszych produktów w zakresie masek.

JAK WYKONANA JEST MASKA MEDYCZNO-CHIRURGICZNA?

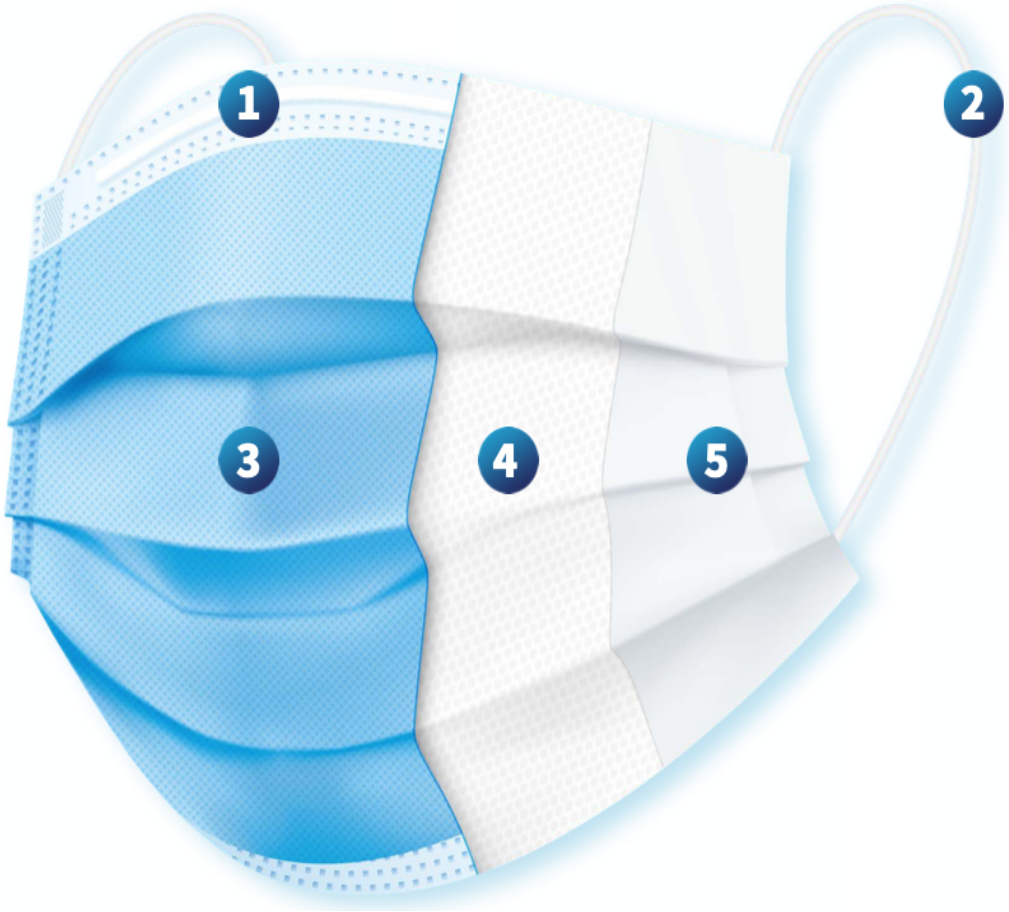
Medyczne maski chirurgiczne wykonane są z wielowarstwowej włókniny filtracyjnej utworzonej z mikrowłókien naładowanych elektrostatycznie.

1 KLAMERKA DO NOSA

Tworzy mocne uszczelnienie dla maksymalnej ochrony i komfortu.

2 ELASTYCZNE PĘTLE NA USZY

Zapewnają bezpieczne dopasowanie



3 ZEWNĘTRZNA WARSTWA OCHRONNA

Niebieska, aby zapewnić, noszenie maski we właśiwy sposób.

4 WARSTWA FILTRUJĄCA: Melt-blown

Skuteczność filtracji bakterii na poziomie ≥ 98%.

5 WEWNĘTRZNA WARSTWA KOMFORTOWA:

Umożliwia użytkownikom wygodne noszenie maski przez dłuższy okres czasu.

Medyczne maski chirurgiczne działają jako bariera ochronna, minimalizując bezpośrednie przenoszenie zainfekowanych płynów lub cząstek wśród pracowników służby zdrowia i pacjentów.

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Przeznaczenie maski

Chirurgiczne maski są przeznaczone do stosowania przez personel medyczny do noszenia ich w środowisku inwazyjnym, zakrywając usta, nos i szczęki użytkownika, zapewniając fizyczną barierę zapobiegającą bezpośredniej penetracji patogenów, mikroorganizmów, wydzieliniu cząstek.

REF

KF-B P01(R)

LATEX FREE

Specyfikacja:

Filtrowanie (BFE):

≤ 98%

Parametr delta P:

(Pa/cm2) ≤ 60

Czystość mikrobiologiczna:

(jtk/g) ≤ 30

Stopień ochrony IP:

(kPa) ≥ 16.0

CERTYFIKACJA SYSTEMU KONTROLI JAKOŚCI

Certyfikat ISO 9001

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1430282**

Certificate Holder: **GuangDong Kingfa Science and Technology Co., Ltd.**
Unified Social Credit Code: 91441802077867032A
Registration Address: No. 28, Delong Road, Qingcheng Dist. Shijiao Town, Qingyuan City, 511545 Guangdong, P. R. China
Operation Address: same as above

Scope: Design and Manufacturing of Modified Plastics;
Design and Manufacturing of Masks and Non-Powered Air-Purifying Particle Respirator

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2020-07-19 until 2023-07-18.
It remains valid subject to satisfactory surveillance audits.
First certification 2014

This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

2020-06-08

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

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CERTYFIKACJA SYSTEMU KONTROLI JAKOŚCI

Certyfikat ISO 13485

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

GuangDong Kingfa Science and Technology Co., Ltd.
No.28, Delong Road, Qingcheng Dist.
Qingyuan City
511545 Guangdong
P.R. China

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

Design and Development, Manufacture and Distribution of Disposable Medical Face Masks (non-sterile)

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:	2020-07-13
Certificate Registration No.:	SX 60150441 0001
An audit was performed. Report No.:	17054679 002
This Certificate is valid until:	2023-07-12

Certification Body

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Date 2020-07-13

Fuxiu Sheng

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

CERTYFIKACJA SYSTEMU KONTROLI JAKOŚCI

Certyfikat ISO 17025 170

China National Accreditation Service for Conformity Assessment

LABORATORY ACCREDITATION CERTIFICATE

(Registration No. CNAS L2647)

Analytical Center of Kingfa Science & Technology Co., Ltd.

(Legal Entity: Kingfa Science & Technology Co., Ltd.)

No.33, Kefeng Road, Science City, Hi-Tech Industrial Development Zone, Guangzhou, Guangdong, China

is accredited in accordance with ISO/IEC 17025: 2017 General Requirements for the Competence of Testing and Calibration Laboratories(CNAS-CL01 Accreditation Criteria for the Competence of Testing and Calibration Laboratories) for the competence to undertake the service described in the schedule attached to this certificate.

The scope of accreditation is detailed in the attached schedule bearing the same registration number as above. The schedule forms an integral part of this certificate.

Effective Date: 2019-09-06

Expiry Date: 2023-07-02

Signed on behalf of China National Accreditation Service for Conformity Assessment

China National Accreditation Service for Conformity Assessment (CNAS) is authorized by Certification and Accreditation Administration of the People's Republic of China (CNCA) to operate the national accreditation schemes for conformity assessment. CNAS is a signatory of the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (ILAC MRA) and the Asia Pacific Accreditation Cooperation Mutual Recognition Arrangement (APAC MRA).

The validity of the certificate can be checked on CNAS website at http://www.cnas.org.cn/english/findanaccreditedbody/index.shtml.

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DECLARATION OF CONFORMITY

Manufacturer:	GUANGDONG KINGFA SCI.&TECH. CO., LTD.
Address of manufacturer:	No.28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China
Product:	Disposable medical mask\Medical Surgical Mask
Model Ref.:	KF-B P01(R)
Class characteristics:	Class I (not sterile or measuring according to Annex IX, Rule 1)
UMDNS-Code:	12458

The product is certified to meet the Essential requirements and relevant provisions of EC Directive: **Medical Devices Directive 93/42/EEC**

Standard(s)/Directive(s):	EN 14683: 2019+AC: 2019(Type IIR)
	EN ISO 10993-1: 2018
	EN ISO 10993-5: 2009
	EN ISO 10993-10: 2010
	EN ISO 13485: 2016
	EN ISO 14971: 2012
	EN ISO 15223-1: 2016
	EN 62366: 2008
	EN 1041: 2008
Conformity assessment procedure:	EC Declaration of Conformity (Annex VII) + Technical Files)
EC representative:	Share Info Consultant Service LLC Repräsentanzbüro
Address:	Heerdter Lohweg 83, 40549 Düsseldorf

This DoC is valid from 14 Nov., 2020.
Authorized by:

CE

Signature
General Manager
Place: Qingyuan, China
Date: Nov.14, 2020

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00315009

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/CA20**		
	Bezeichnung / Name **Bezirksregierung Düsseldorf, Dezernat 24**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Düsseldorf**		Postleitzahl / Postal code **40474**
	Straße, Haus-Nr. / Street, house no. **Cecilienallee 2**		
	Telefon / Phone **+49-211-4750**		Telefax / Fax **+49-211-4752671**
	E-Mail / E-mail **dez24.mpg@brd.nrw.de**		

Anzeige / Notification			
	Registrierdatum bei der zuständigen Behörde Registration date at competent authority **15.09.2020**		Registriernummer / Registration number **DE/CA20/01-share-Info-consultant-262/20**
	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		

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Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00315009

Anzeigender / Reporting organisation (person)			
	Code **DE/0000047946**		
	Bezeichnung / Name **Share Info Consultant Service LLC Repräsentanzbüro**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Düsseldorf**		Postleitzahl / Postal code **40549**
	Straße, Haus-Nr. / Street, house no. **Heerdter Lohweg 83**		
	Telefon / Phone **017670057022**		Telefax / Fax
	E-Mail / E-mail **eu-rep@share-info.cn**		

Hersteller / Manufacturer			
	Bezeichnung / Name **Guangdong KINGFA SCI. & TECH. Co.,LTD**		
	Staat / State **CN**		
	Ort / City **Qingyuan City, Guangdong Province**		Postleitzahl / Postal code **511545**
	Straße, Haus-Nr. / Street, house no. **28 Delong Avenue, Shijiao Town, Qingcheng District**		
	Telefon / Phone **+86 2632 8999**		Telefax / Fax **+86 763 3203108**
	E-Mail / E-mail **sales@kingfa.com.cn**		

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) **Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG**			
	Bezeichnung / Name **Jiehan Li**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Düsseldorf**		Postleitzahl / Postal code **40549**
	Straße, Haus-Nr. / Street, house no. **Heerdter Lohweg 83**		
	Telefon / Phone **017670057022**		Telefax / Fax
	E-Mail / E-mail **eu-rep@share-info.cn**		

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Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00315009

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

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Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00315009

Anzeigender / Reporting organisation (person)			
	Code **DE/0000047946**		
	Bezeichnung / Name **Share Info Consultant Service LLC Repräsentanzbüro**		
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	Telefon / Phone **017670057022**		Telefax / Fax
	E-Mail / E-mail **eu-rep@share-info.cn**		

Hersteller / Manufacturer			
	Bezeichnung / Name **Guangdong KINGFA SCI. & TECH. Co.,LTD**		
	Staat / State **CN**		
	Ort / City **Qingyuan City, Guangdong Province**		Postleitzahl / Postal code **511545**
	Straße, Haus-Nr. / Street, house no. **28 Delong Avenue, Shijiao Town, Qingcheng District**		
	Telefon / Phone **+86 2632 8999**		Telefax / Fax **+86 763 3203108**
	E-Mail / E-mail **sales@kingfa.com.cn**		

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) **Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG**			
	Bezeichnung / Name **Jiehan Li**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Düsseldorf**		Postleitzahl / Postal code **40549**
	Straße, Haus-Nr. / Street, house no. **Heerdter Lohweg 83**		
	Telefon / Phone **017670057022**		Telefax / Fax
	E-Mail / E-mail **eu-rep@share-info.cn**		

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 **Disposable medical mask \ Medical surgical mask**
	Produktbezeichnung / Name of device
	Nomenklaturcode / Nomenclature code
	Nomenklaturbezeichnung / Nomenclature term
	Kategoriecode / Category code **10**
	Kategorie / Category **Produkte zum Einmalgebrauch**
	Kurzbeschreibung deutsch / German short description **Die medizinische Einwegmaske \ Medizinische chirurgische Maske ist für den einmaligen Gebrauch durch medizinisches Fachpersonal und andere Mitarbeiter des allgemeinen Gesundheitswesens vorgesehen, um sowohl Patienten als auch Mitarbeiter des Gesundheitswesens vor der Übertragung von Mikroorganismen, Blut und Körperflüssigkeiten sowie partikulären Materialien zu schützen. Dies ist ein Einweggerät, das nicht steril geliefert wird.** **Modell: KF-B P01 (R)**
	Kurzbeschreibung englisch / English short description **The Disposable medical mask \ Medical surgical mask is intended for single use by medical professionals and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials. This is a disposable device, provided non-sterile.** **Model: KF-B P01(R)**

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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 **Duesseldorf**

Datum
Date **2020-09-09**

Name **Jiehan Li**

Unterschrift
Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority	
Bearbeiter / Person responsible **Frau Nadine Schlingmeier**	Telefon / Phone **0211-475-3853**

RAPORTY Z TESTÓW

(Sprawozdania z testów SGS, TUV, Nelsona)

GUANGDONG KINGFA SCI.&TECH.CO.,LTD.
NO.28 DELONG AVENUE, SHIJIAO TOWN, QINGCHENG DISTRICT, QINGYUAN CITY, GUANGDONG PROVINCE, CHINA

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description	:	(A)Disposable medical mask/Medical surgical mask
Composition	:	(A)Polypropylene
Sample Color	:	(A)Blue
Style No.	:	KF-B P01(R)
Lot No.		25004230
Manufacturer	:	GUANGDONG KINGFA SCI.&TECH.CO.,LTD.
Country of Destination	:	European Union
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Oct 13, 2020
Testing Period	:	Oct 13, 2020 - Oct 26, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

Helen Xuan (Authorized Signatory)

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Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

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RAPORTY Z TESTÓW

SGS

Test Result

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods

Clause 5.2 Performance Requirement

Clause 5.2.2 Bacterial Filtration Efficiency (BFE)
(EN 14683:2019+AC:2019 Annex B)

Sample: A

Test Side	:	Inside
Test Area	:	Approximately 60 cm^2
Flow Rate	:	28.3 L/min
Pre-Conditioning	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Dimensions of test specimen	:	~171mm x 155mm
Positive Control Average	:	2582 CFU
Negative Monitor Count	:	< 1 CFU
Mean Particle Size	:	3.0 ±0.3μm
Test bacteria	:	Staphylococcus aureus ATCC 6538

Test Item	Specimen No.	Result
Bacterial Filtration Efficiency (BFE)	1	99.7%
	2	99.8%
	3	99.8%
	4	99.9%
	5	99.8%

Remark:
1) Performance Requirement: Type I ⩾95%, Type II ⩾98%, Type IIR ⩾98%
2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.

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Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

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Clause 5.2.3 Breathability
(EN 14683 :2019+AC:2019 Annex C)

Sample: A
Test Side : Randomly test in different location (1 around and 4 away from the centric point) on each of the 5 masks
Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
Test Area : 4.9 cm^2
Flow Rate : 8 l/min

Specimen No.	Test Area No.	Different Pressure for each tested area (Pa/cm^2)	The average value for each test specimen (Pa/cm^2)
1	1-1	38.9	34
	1-2	38.3	
	1-3	29.4	
	1-4	32.4	
	1-5	32.2	
2	2-1	32.8	31
	2-2	31.4	
	2-3	30.6	
	2-4	29.6	
	2-5	32.6	
3	3-1	28.2	30
	3-2	29.2	
	3-3	32.0	
	3-4	30.7	
	3-5	27.6	
4	4-1	35.4	32
	4-2	34.1	
	4-3	33.2	
	4-4	30.0	
	4-5	29.2	
5	5-1	35.5	32
	5-2	35.0	
	5-3	31.2	
	5-4	28.6	
	5-5	29.9	

Remark:
1) Performance Requirement: Type I<40 Pa/cm^2, Type II<40 Pa/cm^2, Type IIR<60 Pa/cm^2
2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.

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Clause 5.2.4 Splash Resistance
(ISO 22609 :2004)

Sample: A
Test Blood Pressure : 16.0kPa
Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
Distance of the mask to the tip of cannula : 300±10mm

Test Specimen#	Penetration on inside surface	Conclusion	Test Specimen#	Penetration on inside surface	Conclusion
1	None Seen	Pass	17	None Seen	Pass
2	None Seen	Pass	18	None Seen	Pass
3	None Seen	Pass	19	None Seen	Pass
4	None Seen	Pass	20	None Seen	Pass
5	None Seen	Pass	21	None Seen	Pass
6	None Seen	Pass	22	None Seen	Pass
7	None Seen	Pass	23	None Seen	Pass
8	None Seen	Pass	24	None Seen	Pass
9	None Seen	Pass	25	None Seen	Pass
10	None Seen	Pass	26	None Seen	Pass
11	None Seen	Pass	27	None Seen	Pass
12	None Seen	Pass	28	None Seen	Pass
13	None Seen	Pass	29	None Seen	Pass
14	None Seen	Pass	30	None Seen	Pass
15	None Seen	Pass	31	None Seen	Pass
16	None Seen	Pass	32	None Seen	Pass
Number of Pass:		32			
Overall result:		Acceptable			

Remark:
1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
2) Test was conducted within 60s after removal from conditioning chamber.
3) 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.

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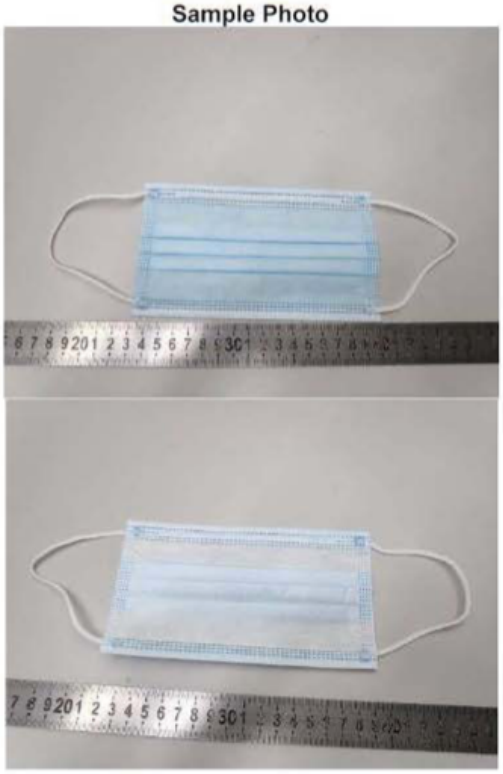
Sample Photo



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

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