Medical Surgical Mask 3NOD-Type IIR

Brand: 3NOD

Type No.: BHKZ-001

Performance standard: EN 14683:2019 + AC:2019(E) Annex B/C/D, tested by TÜV SUD & SGS

Production standards: ISO 13485:2016, tested by Intertek

Inspection: The Netherlands Ministry of Labor and the Tax Investigation Bureau provide the passed proof

Classifications: Type IIR (Non-Sterile), No latex ingredients

Material: Two-layer PP Nonwoven fabric and One-layer BFE99 Meltblown fabric (3 layers)

Mask specifications: Universal, 17,50 x 9,50 cm

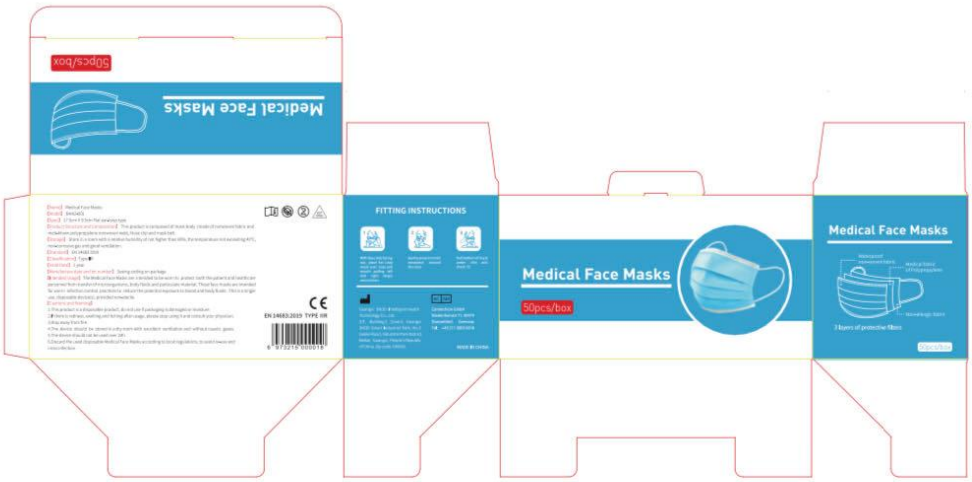
Earloop design: Breathable and comfortable for prolonged wearing

Date of manufacture: From 5th May 2020

Expiration date: 2 years

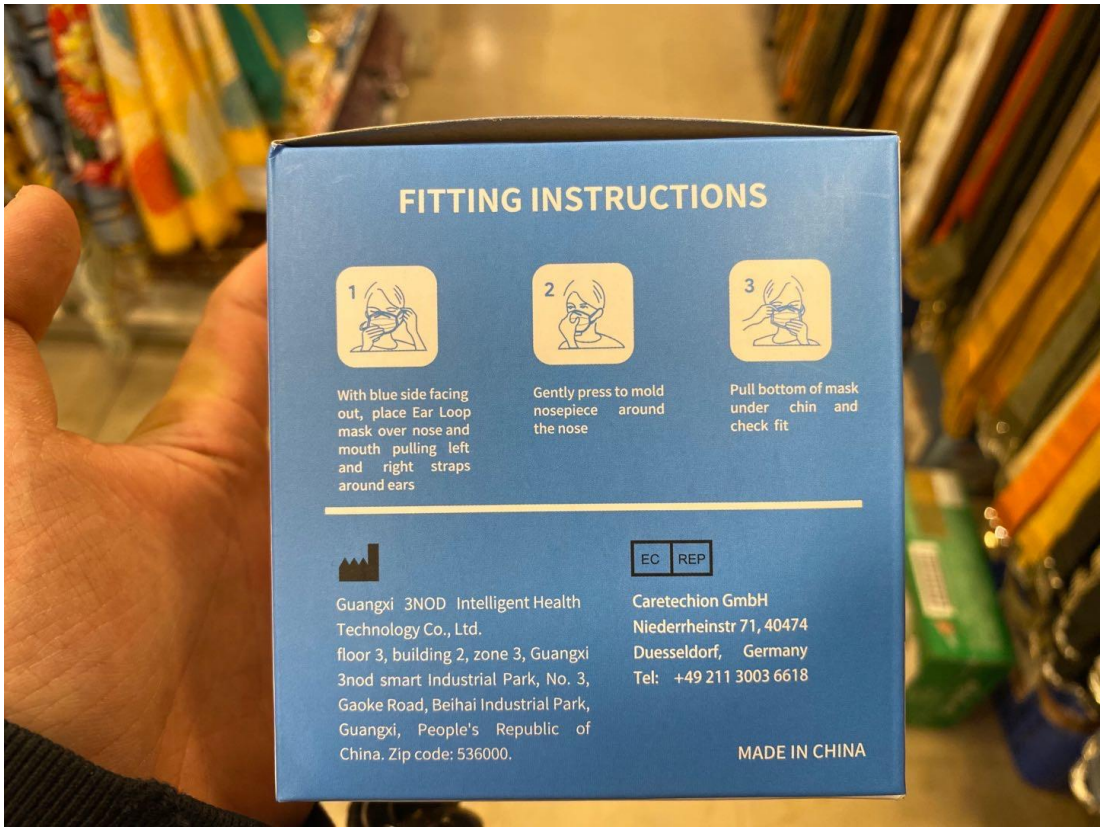
Packing specifications: 50 pcs./box, 40 boxes 2000 pcs./carton, 16 cartons/euro pallet

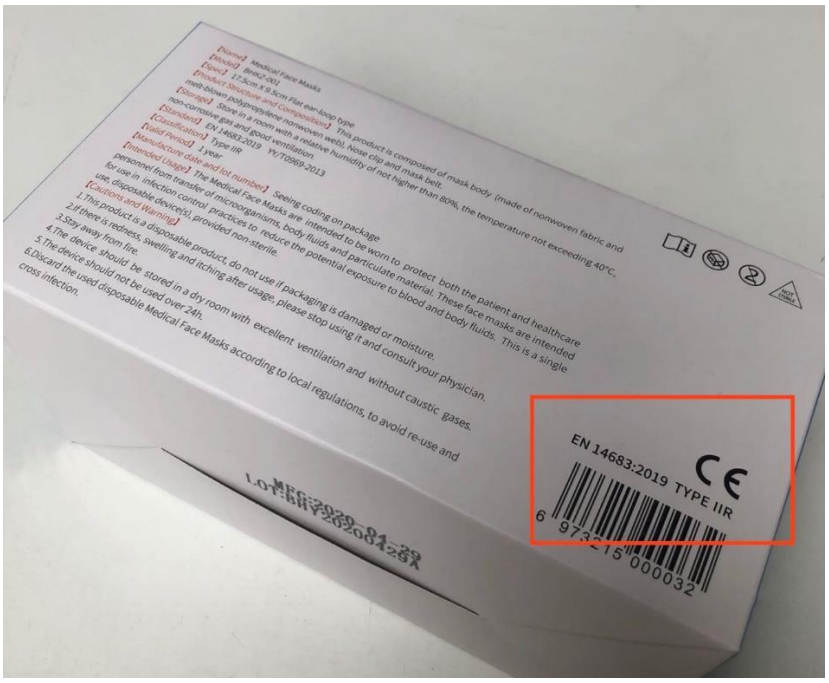
Stock quantities: From 10,000,000 pcs., available in Rotterdam The Netherlands and Frankfurt a/m Germany


50pcs/box
Medical Face Masks
FITTING INSTRUCTIONS
Medical Face Masks
50pcs/box
Medical Face Masks


Medical Face Masks
50pcs/box
Medical Face Masks
50pcs/box


Medical Face Masks
50pcs/box


FITTING INSTRUCTIONS
1
With blue side facing out, place Ear Loop mask over nose and mouth pulling left and right straps around ears
2
Gently press to mold nosepiece around the nose
3
Pull bottom of mask under chin and check fit
EC REP
Guangxi 3NOD Intelligent Health Technology Co., Ltd.
floor 3, building 2, zone 3, Guangxi 3nod smart Industrial Park, No. 3, Gaoke Road, Beihai Industrial Park, Guangxi, People's Republic of China. Zip code: 536000.
Caretechion GmbH
Niederrheinstr 71, 40474
Duesseldorf, Germany
Tel: +49 211 3003 6618
MADE IN CHINA


EN 14683:2019 TYPE IIR
CE


Guangxi 3NOD Intelligent Health Technology Co., Ltd.
3/F, Building 2, Zone 4, Guangxi 3NOD Smart Industrial Park,
No.3 Gaoke Road, Industrial Park District, Beihai, Guangxi,
People's Republic of China. Zip code: 536000.
EC REP
Caretechion GmbH
Niederrheinstr 71, 40474 Duesseldorf, Germany
Tel: 49 211 3003 6618
Manufacture date and lot number on printed code
CE
EN 14683:2019 TYPE IIR
MADE IN CHINA


Wij zoeken
altijd vakmensen!
Brentano


Rosa
Spier
Huis
Medical Face Masks
Medical Face Masks
Medical Face Masks
Medical Face Masks

EN 14683:2005

This European Standard specifies construction and performance requirements, and test methods for surgical masks intended to limit the transmission of infective agents from staff to patients and (in certain situations vice-versa) during surgical procedures in operating theatres and other medical settings with similar requirements. This European Standard is not applicable to masks intended exclusively for the personal protection of staff.
This standard is intended to help facilitate the choice of surgical face masks in the European Market by standardizing the information and performance data required for the masks.
There are three test methods used to classify surgical masks:

1. Bacterial Filtration Efficiency in vitro (BFE) (ASTM F2101-07**)**
This test is used to determine the amount of infective agent that is retained by the surgical facemask, which is directly related to the amount of bacteria released through the mask into the air of the surgical theatre.
Classification:
BFE => 95% TYPE I
BFE => 98% TYPE II

2. Breathing Resistance (Delta P)
This test is used to determine the resistance airflow of the facemask.
Classification:
TYPE I & II (non splash resistant) = < 29.4 Pa/cm2
TYPE IR & IIR (splash resistant) = < 49.0 Pa/cm2

3. Splash Resistance (ASTM F1862-07**)**
This test is used to determine the resistance penetration of potentially contaminated fluid splashes.
Classification:
TYPE I & TYPE II not applicable
TYPE IR & TYPE IIR >120 mmHg
120 mmHg is a minimum value. It corresponds to the average systolic arterial blood pressure, and intends to protect against ruptures in small arteries causing small sprays of blood. Some products off protection even in excess of the 120 mmHg.

Minimum Performance Requirements According to the New Facemask Standard EN14683

EU Standard Class	Bacterial Filtration Efficiency	Breathing Resistance (Pa/cm2)	Splash Resistance (mmHg)
Type I	95%	< 29.4	NA
Type IR	95%	< 49.0	> 120
Type II	98%	< 29.4	NA
Type IIR	98%	< 49.0	> 120

DIMDI - Deutsches Institut für Medizinische Dokumentation und Information

Anzeige

Anzeige

Meldungsnummer	00162146
Formularnummer	00303238
Typ der Anzeige	Erstanzeige Medizinprodukt
Anzeigender nach § 25 MPG	Bevollmächtigter
Datum der Weiterleitung an zuständige Behörde	2020-04-23
Bearbeitungsstatus	weitergeleitet zur Behörde
Bearbeitungsdatum	2020-04-23
Erstellungsdatum	2020-04-23

Angaben zum Anzeigenden

Code	DE/0000048026
Bezeichnung	Caretechion GmbH
Staat	Deutschland
Land	Nordrhein-Westfalen
Postleitzahl	40474
Ort	Düsseldorf
Straße/Haus-Nr.	Niederrheinstraße 71
Telefon	+49 211 300 366 18
E-Mail	jian.wang@caretechion.de

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG

Name	Ingo Becker
Staat	Deutschland
Land	Nordrhein-Westfalen
Postleitzahl	50374
Ort	Erftstadt
Straße/Haus-Nr.	Elly-Heuss-Knapp-Weg, 26
Telefon	022356892667
Telefax	—
E-Mail	ingo.becker@ka-becker.de

Zuständige Behörde

Code	DE/CA20
Bezeichnung	Bezirksregierung Düsseldorf, Dezernat 24
Staat	Deutschland
Land	Nordrhein-Westfalen
Straße/Haus-Nr.	Cecilienallee 2
Postleitzahl	40474
Ort	Düsseldorf
Telefon	+49-211-4750
Telefax	+49-211-4752671

E-Mail	dez24.mpg@brd.nrw.de

Produkt

Produkttyp	nichtaktives Medizinprodukt
Klasse	I
App (Software auf mobilen Endgeräten)	Nein
Tragen alle Medizinprodukte eine CE-Kennzeichnung und werden innerhalb ihrer Zweckbestimmung eingesetzt?	—

Medizinprodukt

Handelsname	Medical Face Masks
Allgemeine Produktbezeichnung	—
Nomenklaturcode	12-458
Nomenklaturbezeichnung	Maske, Chirurgie
Kategorie	Produkte zum Einmalgebrauch
Kurzbeschreibung in Deutsch	Die Produkte sollen zum Schutz vor der Ausbreitung oder Übertragung infektiöser Keime bei chirurgischen Eingriffen in Operationssälen und anderen medizinischen Einrichtungen getragen werden. Einmalgebrauch und nicht steril.
Kurzbeschreibung in Englisch	The Disposable Medical Face Masks are intended to be worn to protect against the spread or transmission of infectious germs during surgical interventions in operating theatres and other medical facilities. Single-use and non-sterile.

1.Hersteller

Bezeichnung	Guangxi 3NOD Intelligent Health Technology Co., Ltd.
Staat	China
Ort	Beihai
Postleitzahl	536000
Strasse	Third floor, Building D02, Guangxi 3NOD Smart Industrial Park, No.3 Gaoke Road, Beihai Industrial Park
Telefon	+86-19806658677
Telefax	—
E-Mail	Songgang.zhan@3nod.com.cn

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00303238

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		Registriernummer / Registration number
	Typ der Anzeige / Notification type S 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 S 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/0000048026**		
	Bezeichnung / Name **Caretechion GmbH**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Düsseldorf**		Postleitzahl / Postal code **40474**
	Straße, Haus-Nr. / Street, house no. **Niederrheinstraße 71**		
	Telefon / Phone **+49 211 300 366 18**		Telefax / Fax
	E-Mail / E-mail **jian.wang@caretechion.de**		

Hersteller / Manufacturer			
	Bezeichnung / Name **Guangxi 3NOD Intelligent Health Technology Co., Ltd.**		
	Staat / State **CN**		
	Ort / City **Beihai**		Postleitzahl / Postal code **536000**
	Straße, Haus-Nr. / Street, house no. **Third floor, Building D02, Guangxi 3NOD Smart Industrial Park, No.3 Gaoke Road, Beihai Industrial Park**		
	Telefon / Phone **+86-19806658677**		Telefax / Fax
	E-Mail / E-mail **Songgang.zhan@3nod.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 **Ingo Becker**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Erftstadt**		Postleitzahl / Postal code **50374**
	Straße, Haus-Nr. / Street, house no. **Elly-Heuss-Knapp-Weg, 26**		
	Telefon / Phone **022356892667**		Telefax / Fax
	E-Mail / E-mail **ingo.becker@ka-becker.de**		

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

Medizinprodukt (Erstmaliges Inverkehrbringen) / Medical device (First placing on the market)	
	Klasse / Class S 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 S nein / no
	Nummer(n) der Bescheinigung(en) / Certificate number(s)
	Handelsname des Produktes / Trade name of the device **Medical Face Masks**
	Produktbezeichnung / Name of device
	Nomenklaturcode / Nomenclature code **12-458**
	Nomenklaturbezeichnung / Nomenclature term **Maske, Chirurgie**
	Kategoriecode / Category code **10**
	Kategorie / Category **Produkte zum Einmalgebrauch**
	Kurzbeschreibung deutsch / German short description **Die Produkte sollen zum Schutz vor der Ausbreitung oder Übertragung infektiöser Keime bei chirurgischen Eingriffen in Operationssälen und anderen medizinischen Einrichtungen getragen werden. Einmalgebrauch und nicht steril.**
	Kurzbeschreibung englisch / English short description **The Disposable Medical Face Masks are intended to be worn to protect against the spread or transmission of infectious germs during surgical interventions in operating theatres and other medical facilities. Single-use and non-sterile.**

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 **Erftstadt**

Datum
Date **2020-04-23**

Name **Ingo Becker**

Unterschrift
Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority			
	Bearbeiter / Person responsible		Telefon / Phone

EC DECLARATION OF CONFORMITY

REGULATION 745/2017 ON MEDICAL DEVICE

Name and address of the manufacturer: /	Guangxi 3NOD Intelligent Health Technology Co., Ltd. Third Floor, Building D02, Guangxi 3NOD Smart Industrial Park, No.3 Gaoke Road, Beihai Industrial Park, Beihai 53600, China.
EC Authorized Representative:/	Caretechion GmbH Niederrheinstr 71,40474 Düesseldorf, Germany

We, as the manufacturer, are exclusive responsible for the declaration of conformity. Herewith declare that the state medical device meets the provisions of Medical Device Regulation of EU 2017/745:2017 and its transportations in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Name of the medical device: /	Medical Face Masks Model: BHKZ-001
UMDNS Code:/	12458
Basic UDI-DI:/	N/A
Intended purpose: /	The Medical Face Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.
Classification/	Rule1, Class I CND code: T020601 Standard Surgical Face Masks according to annex VIII of directive EU 2017/745(MDR) /
CS reference: /	NA
Conformity assessment: /	Declare the conformity of the abovementioned products by issuing this EU Declaration of Conformity after drawing up the technical documentation set out in Annexes II and III of Regulation (EU) 2017/745 / according to Article 52(7) of Regulation (EU) 2017/745 /

Beihai 2020-04-20	General Manager
Place, date	Name and function

SUBJECT	**Physical & Microbiological Test**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	**Guangxi 3NOD Intelligent Health Technology Co., Ltd**
CLIENT ADDRESS	Third floor, building D02, guangxi 3nod Intelligent industrial park, no.3 gaoke road, beihai industrial park
TEST PERIOD	02-Apr-2020~11-Apr-2020

Prepared By	**Authorized By**
Bella Xu	Leo Liu
(Bella Xu)	(Leo Liu)
Report Drafter	Authorized Signatory

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

TEST REPORT

Sample Description	:	Medical face masks
Sample Quantity	:	60 pieces
Lot Number/Batch Code	:	/
Specification	:	BHKZ-001
Size	:	/
Style No.	:	Adult
Type of Mask	:	Type IIR
Brand Name	:	/

Remark: The above information was provided by applicant.

Summary of Test Results

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

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

Photo of Samples

Results

No.	Test Item	Test Result
1	Bacterial Filtration Efficiency (BFE) Test	Specimen 1#: 99.8% Specimen 2#: 99.9% Specimen 3#: 99.7% Specimen 4#: 99.6% Specimen 5#: 99.7%
2	Differential Pressure Test	54.0 Pa/cm^2
3	Synthetic Blood Penetration Test	Specimen 1#~13#: None seen
4	Microbial Cleanliness Test	Specimen 1#: 25 CFU/g Specimen 2#: 15 CFU/g Specimen 3#: 22 CFU/g Specimen 4#: 13 CFU/g Specimen 5#: 18 CFU/g

Bacterial Filtration Efficiency (BFE) Test

1. Purpose

For evaluating the bacterial filtration efficiency (BFE) of mask.

2. Sample description was given by client

Sample description : Medical face masks
Specification : BHKZ-001
Lot Number : /
Sample Receiving Date : 2020-04-02

3. Test Method

EN 14683:2019+AC:2019(E) Annex B

4. Apparatus and materials

4.1 *Staphylococcus aureus* ATCC 6538.
4.2 Peptone water.
4.3 Tryptic Soy Broth(TSB).
4.4 Tryptic Soy Agar(TSA).
4.5 Bacterial filtration efficiency test apparatus.
4.6 Six-stage viable particle Anderson sampler.
4.7 Flow meters.

5. Test specimen

5.1 As requested by client, take a total of 5 test specimens.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5)°C and (85±5)% relative humidity.

6. Procedure

6.1 Preparation of the bacterial challenge: Dilute the cultutre in peptone water to achieve a concentration of approximately 5×10^5 CFU/mL.
6.2 Adjust the flow rate through the Anderson sampler to 28.3 L/min.
6.3 Deliver the challenge to the nebulizer using a syringe pump. Purge tubing and nebulizer of air bubbles.
6.4 Perform a positive control run without a test specime to determine the number of viable aerosol particles being generated. The mean particle size (MPS) of the aerosol will also be calculated from the results of these positive control plates.
  6.4.1 Initiate the aerosol challenge by turning on the air pressure and pump connected to the nebulizer. Immediaterly begin sampling the aerosol using the Anderson sampler.
  6.4.2 Time the challenge suspension to be delivered to the nebulizer for 1 min.
  6.4.3 Time the air pressure and Anderson sampler to run for 2 min.
  6.4.4 At the conclusion of the positive control ran, remove plates from the Anderson sampler.
6.5 Place new agar plates into Anderson sampler and clamp the test specimen into the top of the Anderson sampler, with the inside of the specimen facing towards the bacterial challenge (test area: 77cm^2).
6.6 Repeat the challenge procedure for each test specimen.
6.7 Repeat a positive control after completion of the sample set.
6.8 Perform a negative control run by collecting a 2 min sample of air from the aerosol chamber. No bacterial challenge should be pumped into the nebulizer during the collection of the negative control.
6.9 Incubate agar plates at (37±2)°C for (20 to 52) h.
6.10 Count each of the six-stage plates of the Anderson sampler.

7. Calculation

Total the count from each of the six plates for the test specimens and positive controls, as specified by the manufacture of Anderson sampler. The filtration efficiency percentages are calculated as follows:

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

T is the total plate count for the test specimen.

C is the mean of the total plate counts for the two positive controls.

8. Test results*

P Value / Stage Number	Positive Control (A)	Positive Control (B)	Negative Control	Specimen 1#	Specimen 2#	Specimen 3#	Specimen 4#	Specimen 5#
1	26	42	0	0	0	0	0	0
2	65	105	0	0	0	0	0	0
3	206	221	0	0	0	0	0	0
4	269	387	0	0	0	2	0	1
5	963	1109	0	0	0	5	6	4
6	597	543	0	5	1	1	3	2
Total (*T*), CFU	2126	2407	<1	5	1	8	9	7
Average (C), CFU	$2.3x10^3 = (P_A+P_B) / 2$							
BFE ,%				99.8	99.9	99.7	99.6	99.7
Requirements	≥ 98							
Remarks	*P* is the value of corresponding corrected particle counts as specified by the manufacturer of the cascade impactor. *T* is the total of *P* value for the test specimen. *C* is the mean of the total of *P* value of the two positive controls.							

Differential pressure Test

1.Purpose

The purpose of the test was to measure the differential pressure of masks.

2.Sample description was given by client

Sample description : Medical face masks
Specification : BHKZ-001
Lot Number : /
Sample Receiving Date : 2020-04-02

3.Test Method

EN 14683:2019+AC:2019(E) Annex C

4. Apparatus and materials

Differential pressure testing instrument

5.Test specimen

5.1 Test specimen are complete masks or shall be cut from masks. Each specimen shall be able to provide 5 different circular test areas of 2.5 cm in diameter.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5)°C and (85±5)% relative humidity.

6. Procedure

6.1 Without a specimen in place, the holder is closed and the differential manometer is zeroed. The pump is started and the flow of air adjusted to 8 L/min.
6.2 The pretreated specimen is placed across the orifice (total area 4.9cm^2, test area diameter 25mm) and clamped into place so as to minimize air leaks.
6.3 Due to the presence of an alignment system the tested area of the specimen should be perfectly in line and across the flow of air.
6.4 The differential pressure is read directly.
6.5 The procedure described in steps 6.1-6.4 is carried out on 5 different areas of the mask and readings averaged.

Results:

Specimen	Test Results* (Pa/cm^2)	Average (Pa/cm^2)	Requirements	Judgement
1#	57.0	54.0	< 60	Pass
2#	56.4			
3#	53.7			
4#	53.1			
5#	49.8			

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

Synthetic Blood Penetration Test

1.Purpose

For evaluation of resistance of masks to penetration by a fixed volume of synthetic blood at a high velocity.

2.Sample description was given by client

Sample description	:	Medical face masks
Specification	:	BHKZ-001
Lot Number	:	/
Sample Receiving Date	:	2020-04-02

3.Test Method

ISO 22609:2004

4.Apparatus and materials

4.1 Synthetic blood.
4.2 Tensiometer.
4.3 Synthetic blood penetration test apparatus;
4.4 Targeting plate.
4.5 Air pressure source.
4.6 Ruler.
4.7 Balance.
4.8 Controlled temperature and humidity chamber.

5.Test specimen

5.1 As requested by client, take a total of 13 test specimens.
5.2 Prior to testing, condition all test specimens for a minimum of 4h at (21±5)°C and (85±5) % relative humidity.

6.Procedure

6.1 Prepare the synthetic blood (40~44 mN/m) for the test.
6.2 Determine the density of the synthetic blood.
6.3 Fill the reservoir with new synthetic blood.
6.4 Position the test specimen 30.5 cm (12 in.) from the exit of the canula.
6.5 Set the reservoir pressure to the approximate pressure.
6.6 Place the targeting plate approximately 1 cm away from the mask.
6.7 Set the valve timer to 0.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).

6.8 Set the valve timer to 1.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).

6.9 Calculate the difference in weight of the two spurts. For a test fluid with a density of 1.003, Table 1 gives the target difference in weight plus lower and upper limits for a velocity range within 2% of the target.

Table 1 Target weight difference

Fluid Pressure (mmHg)	Weight difference for 1 s difference in spurt duration (g)		
	Min.	Target	Max.
120	3.002	3.063	3.124

6.10 Adjust the reservoir pressure and repeat steps 6.7 to 6.9 until the weight difference is within the target range.

6.11 Record the weight difference for the spurts exiting the nozzle.

6.12 Record the pressure in the reservoir.

6.13 Set the valve time to 0.5 s. Collect and weigh the amount of fluid passing through the targeting hole.

6.14 Set the valve time to 1.5 s. Collect and weigh the amount of fluid passing through the targeting hole.

6.15 The difference in weight between the 0.5 s and 1.5 s spurts through the targeting plate shall be within +2 % ~ -5 % of the difference in weight from the nozzle.

6.16 If the differential weight is less than 95 % of the weight difference exiting the nozzle, check the aim of the stream to make sure it is passing cleanly through the targeting hole.

6.17 If the differential weight is more than 102 % of the weight difference exiting the nozzle, repeat the weight measurements exiting the nozzle (steps 6.7 to 6.11).

6.18 For standard synthetic blood, the timer duration can be estimated using the formula:
(p is the density of the test fluid.) $t = 0.5 + (2\times p$ - g at 0.5 s) / (g at 1.5 s - g at 0.5 s).

6.19 Record the timer setting to use as the starting point for subsequent testing.

6.20 Mount a test specimen on the specimen holding fixture. If the mask contains pleats, spread the pleats out when mounting the mask onto the fixture to present a single layer of material as the target area.

6.21 Squirt the synthetic blood onto the test specimen for the calculated time. Ensure that the synthetic blood hits the target area of mask.

6.22 Inspect the inside surface for synthetic blood penetration within 10 s of squirting the synthetic blood against the target area.

6.23 Report the results (none / penetration) for each test specimen at the test pressure.

Results:

Specimen	Test Results*	Requirements	Judgement
1#	None Seen	Pass Pressure at 16.0 kPa (120mmHg)	Pass
2#	None Seen		Pass
3#	None Seen		Pass
4#	None Seen		Pass
5#	None Seen		Pass
6#	None Seen		Pass
7#	None Seen		Pass
8#	None Seen		Pass
9#	None Seen		Pass
10#	None Seen		Pass
11#	None Seen		Pass
12#	None Seen		Pass
13#	None Seen		Pass

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

Microbial Cleanliness Test

1. Purpose

The purpose of the test was to measure microbial cleanliness of mask.

2. Sample description was given by client

Sample description	:	Medical face masks
Specification	:	BHKZ-001
Lot Number	:	/
Sample Receiving Date	:	2020-04-02

3. Test Method

According to EN ISO 11737-1:2018 to determine the microbial cleanliness of mask material, and refer to the procedure as described in EN 14683:2019+AC:2019(E) Annex D

4. Apparatus and materials

4.1 Orbital shaker.
4.2 0.45 um filter.
4.3 Tryptic Soy Agar (TSA).
4.4 Sabouraud Dextrose Ager (SDA) with chloramphenicol.
4.5 Formula of Extraction Liquid: 1g/L peptone, 5g/L NaCl and 2g/L Tween 20.
4.6 Extraction apparatus.

5. Test specimen

5.1 As requested by client, take a total of 5 mask samples.
5.2 Mask samples for testing are provided in the original primary packaging.
5.3 Condition at (18 to 26)℃ and (45 to 65)% relative humidity during testing.

6. Procedure

6.1 Five test specimens are selected from the top, bottom and 3 randomly chosen marks.
6.2 The mask is aseptically removed from the packaging and placed in a sterile 500 mL bottle containing 300 mL of extraction liquid.
6.3 The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm.
6.4 After extracting, 100mL of the extraction liquid is filtered through a 0.45 um filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 mL aliquot of the same extraction liquid is filtered in the same way and the filter plated on SDA for fungi enumeration.
6.5 The plates are incubated for 3 days at 30ºC and 7 days at (20 to 25)ºC for TSA and SDA plates respectively.
6.6 Calculate the colonies of each agar plate.

7. Calculation

For each test specimen calculate the microbial cleanliness as follows by counting the total colonies of the TSA and SDA plates.

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
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Phone : +86 (21) 6037 6375
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Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

Results*:

Specimen	Colonies of the TSA Plate	Colonies of the SDA Plate	Microbial Cleanliness, (CFU/g)	Requirements	Judgement
1#	13	12	25	According to EN ISO 11737-1:2018 the microbial cleanliness of the mask shall be ≤30 CFU/g tested.	Pass
2#	9	6	15		
3#	9	13	22		
4#	9	4	13		
5#	13	5	18		

Note:

1.*denotes this test was carried out by external laboratory assessed as competent.

2.This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
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Phone : +86 (21) 6037 6375
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Regional Head Office:
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No.151 Heng Tong Road Shanghai
200 070 P.R.China

GUANGXI 3NOD WISDOM HEALTH TECHNOLOGY CO. LTD.
THIRD FLOOR, BUILDING D02. GUANGXI 3NOD WISDOM INDUSTRIAL PARK, NO. 3 GAOKE ROAD, BEIHAI INDUSTRIAL PARK, CHINA.

The content of this test report is extracted from the test report number T32020240104SN where the sample is claimed to be identical.

The following samples were submitted and identified on behalf of the client as:

MEDICAL FACE MASK

SGS Case No.	:	CA320202404899
Style / Item No.	:	KZM-001
Lot No. / Batch Code	:	NOT PROVIDED
Sample Description	:	BLUE MASK
Sample Receiving Date	:	APR 03, 2020
Test Performing Date	:	APR 03 TO MAY 18, 2020

Test Requested : Please refer to the result summary.

Test Method & Results : Please refer to next page(s).

Result Summary :

Test Requested	Result Summary
ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks	See Result

****

Signed for and on behalf of
SGS Hong Kong Ltd.

Au Kam Chi, Gigi
Technical Manager

ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks

Scope : This specification covers testing and requirements for materials used in the construction of medical face masks that are used in providing healthcare services such as surgery and patient care. This specification provides for the classification of medical face mask material performance.

Clause	Test Items/requirement	Test Result Summary
5	**Classification**	See Table 1
6	**Requirements**	
6.1	The properties of the medical face mask material shall conform to the specifications requirements in Table 1, as tested in accordance with Section 9.	
	Bacterial filtration efficiency (ASTM F2101)	> 98%
	Differential pressure (EN 14683:2019 Annex C)	< 6.0 mm H_2O/cm^2
	Sub-Micron Particulate Filtration (ASTM F2299)	> 98%
	Resistance to penetration by synthetic blood (ASTM F1862)	Penetration not seen at 120 mm Hg
6.2	Flammability 16 CFR Part 1610	Class 1

Table 1 Medical Face Mask Material Requirements by Performance Level

Characteristics	Level 1 Barrier	Level 2 Barrier	Level 3 Barrier
Bacterial filtration efficiency, %	≥ 95	≥ 98	≥ 98
Differential pressure, mm H_2O/cm^2	< 5.0	< 6.0	< 6.0
Sub-micron particulate filtration efficiency at 0.1 micron, %	≥ 95	≥ 98	≥ 98
Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result#	80	120	160
Flame spread	Class 1	Class 1	Class 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.

Result 1 Bacterial filtration efficiency ASTM F2101-19

Test Side	:	White Color (Inside)
Pre-Conditioning	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Dimensions of test specimen	:	~ 174 mm x 170 mm
BFE Test Area	:	~ 40 cm^2
BFE Flow Rate	:	28.3 l/min
Test bacteria	:	Staphylococcus aureus ATCC 6538
Mean Particle Size	:	2.7 μm
Positive Control Average	:	2.7 x 10^3 CFU
Negative Monitor Count	:	< 1 CFU

Test Specimen	Percent BFE (%)
1	99.9
2	99.8
3	99.9
4	99.9
5	99.9

Result 2 Differential pressure EN14683:2019+AC:2019 Appendix C

Test Side	:	White Color (Inside)
Pre-Conditioning	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Dimensions of test specimen	:	~ 174 mm x 170 mm
Flow Rate	:	8 l/min

Test Specimen	ΔP (mm H_2O/cm^2)	ΔP (Pa/cm^2)
1	3.8	37.0
2	3.8	37.0
3	3.7	36.0
4	3.8	37.0
5	3.7	36.0

Result 3 Sub-Micron Particulate Filtration ASTM F2299/F2299M-03 (Reapproved 2017)

Test Side	:	Blue Side
Pre-Conditioning	:	Minimum of 4 hours at 21±3°C and 30-50±5% R.H.
Test Condition	:	20 ° C and 24% R.H.
Test Area	:	91.5 cm^2
Particle Size	:	0.1 μm
Average Filtration Efficiency	:	99.69%
Standard Deviation	:	0.052

Test Specimen	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	49	12,992	99.62
2	35	13,208	99.73
3	36	13,293	99.73
4	49	13,865	99.65
5	41	14,439	99.72

Result 4 Resistance to penetration by synthetic blood ASTM F1862/F1862M-17

Test Side	:	Blue Side
Pre-Conditioning	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Test Condition	:	20.5 ° C and 22% R.H.
Test Pressure	:	120 mmHg
No of Test Specimen Tested	:	32
No of Test Specimen Passed	:	32

Test Specimen #	Synthetic Blood Penetration
1-32	None Seen

Result 3 Flammability Test of Clothing Textiles (16 CFR Part 1610 - October 20, 2008 Edition)

Sample	:	Fabric cut from submitted sample
Fabric Surface	:	Plain (Face)
Test Specimen Direction	:	Length

	As Received	
	Flame Spread (sec.)	Burn Code
(1)	--	IBE
(2)	--	IBE
(3)	--	IBE
(4)	--	IBE
(5)	--	IBE
Flammability Classification:		Class 1
Requirement:		Class 1

Remarks:

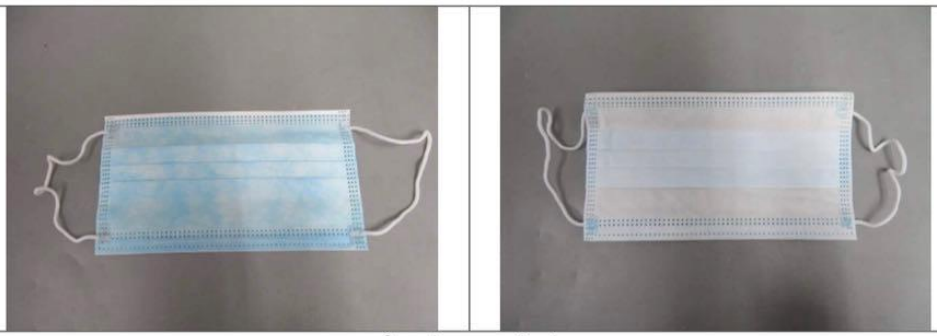
1. **Class 1 – Normal Flammability**
   Class 1 textiles exhibit normal flammability and are acceptable for use in clothing.
   Test Criteria for plain surface textile fabric:
   (A) There are no burn times; or
   (B) There is only one burn time and it is equal to or greater than 3.5 seconds; or
   (C) The average burn time of two or more specimens is equal to or greater than 3.5 seconds.
2. Disposable fabrics and garments shall not apply to be refurbished before testing.

Burn Code Description:

IBE = Ignited, but extinguished

Note : All the test results except Flammability test contained in this Test Report was conducted by a SGS assessed competent subcontractor laboratory

Photo Appendix



Sample as received

*** End of Report ***

Meetrapport/measurement report nr.	293		**DATE**		22-05-2022	**Lighthouse 3100 output**					
Client name	Colorfone		**Mouth Mask Brand**		3NOD						
adress	Melbournestraat 68		**Mouth Mask Type**		Medical						
email	info@colorfone.nl		**sterilsed/new**		New / type 2R						
Phone	0104298180										
GreenCycl BV			**Operator Name**		PVS						
3454 PV De Meern			**time**		14:38						
info@greencycl.nl			**FOTO nr**								
Tel.: 030 – 602 38 30											
banchmarking											
Flow	**1F^3**										
measurement time	**1min**										
Self Imbibition Filter											
particle size	*0.3*	*0.5*	*1.0*	*3.0*	*5.0*						
environment particles 1	474821	58438	13020	886	656						
environment particles 2	474821	58438	13020	886	656						**type**
avarage	**474821**	**58438**	**13020**	**886**	**656**					**BFE**	IIR
particles counted	0.3 mu	0.5 mu	1.0 mu	3 mu	5 mu	percentage particles filtered [%]					
Disposable Medical Mask 3NOD Type-IIR						0.3	0.5	1.0	3.0	5.0	
Brand: 3NOD	178618	13665	1728	0	0	62	77	87	100	100	
Type No.: BHKZ-001	226651	18132	2386	0	0	52	69	82	100	100	
mean	**202634,5**	**15898,5**	**2057,0**	**0,0**	**0,0**	**57,3**	**72,8**	**84,2**	**100,0**	**100,0**	
Important note:	• Measurements are done with dry environmental particles according to our own standards. The percentages indicate the percentage of particles filtered per particle size category (0.3 0.5 1 and 5 mu) in a standardised volume of air. Measurements are done at 28 liter/min. More information can be found on www.greencycl.org..										
	• Each sample is 1 mask. All measurements will be published anonymously on www.greencycl.org.										
	• Sample 1&2 represent 2 different locations on the first masker										

Intertek Testing Services Ltd., Shanghai
Floor 2, No. 15&16, Lane 1988, Changzhong Road, Shanghai
Telephone (86) 21 5339 7742
Website: https://www.intertek.com.cn/

2020-06-03

To Whom It May Concern

This is to confirm that the Initial audit was carried out as follows:

Company: Shenzhen 3Nod Electronic Co., Ltd

Address: 3rd floor, Zone 1, Building 14, Hengmingzhu science and technology industrial park, Xinqiao tongfu industrial park, Shajing Street, Baoan, Shenzhen, Guangdong, 518105, China

Standard: ISO13485:2016

Audit Date: Stage1: 15-17, May, 2020 Stage2: 28-31, May, 2020

Scope: Manufacture of disposable medical face masks(non-sterile).

The corrective action plan proposed by the company are acceptable, therefore the certificate for a Quality Management System should be issued.

Yours sincerely,

Intertek Testing Services Ltd., Shanghai

Mr. Shizhen Ke
Manager, Medical device, China
Business Assurance, Intertek

Inspectie SZW
Ministerie van Sociale Zaken en Werkgelegenheid

> Retouradres Postbus 90801 2509 LV Den Haag

Colorfone
t.a.v. De heer H Cai
Melbournestraat 68
3047 BJ ROTTERDAM

Inspectie SZW

Parnassusplein 5
2511 VX Den Haag
Postbus 90801
2509 LV Den Haag
www.inspectieszw.nl

Contactpersoon
Medewerker afd.
Inspectieondersteuning

T +31 (0)70 333 6383

Onze referentie
2010243/01

Datum 4 juni 2020
Betreft Afhandeling inspectie

Geachte heer Cai,

Op woensdag 3 juni 2020 brachten de heer R.W van de Spoel (FIOD) en ondergetekende een inspectiebezoek aan Colorfone. Tijdens deze inspectie, gericht op de naleving van het Warenwetbesluit Persoonlijke beschermingsmiddelen en Directive 2016/425 en 2020/403, zijn geen overtredingen geconstateerd.

Hoogachtend,

M.A.M. Hek
Inspecteur Markttoezicht Productveiligheid Inspectie SZW

检 验 报 告

TEST REPORT

报告编号：WT204017509

委 托 单 位 ： 广西三诺智慧健康科技有限公司

委托单位地址 ： 北海市工业园区高科路3号广西三诺智慧产业园区D02栋三楼

样 品 名 称 ： 一次性使用医用口罩

型号/规格/等级： 17.5cm*9.5cm

检 验 类 别 ： 送样检验

检 验 地 点 ： 龙华实验基地Longhua Experimental Base

深圳市计量质量检测研究院
（检验检测专用章）

批准人： 何行月 陈晶

签发日期：2020年04月14日

签名 ： 何行月 陈晶

深圳市计量质量检测研究院
Shenzhen Academy of Metrology & Quality Inspection

检 验 报 告

样品信息：

样品名称： 一次性使用医用口罩
商标： 三诺电子
型号/规格/等级： 17.5cm*9.5cm
样品编/批号： 20200331
生产日期： 2020-03-31
生产单位： 广西三诺智慧健康科技有限公司
生产单位地址： 北海市工业园区高科路3号广西三诺智慧产业园区D02栋三楼
样品数量： 100个　　抽样基数： ----------
抽样地点： ----------
抽样人员： ----------
检前样品描述： 正常。Normal.

客户信息：

委托单位： 广西三诺智慧健康科技有限公司
委托单位地址： 北海市工业园区高科路3号广西三诺智慧产业园区D02栋三楼
委托单位电话： 13602632799
邮政编码： ----------
受检单位： ----------

检验信息：

委托日期： 2020年04月01日　　委托单号： 8234579
检验类别： 送样检验　　获样方式： 送样
检验日期： 2020年04月01日 至 2020年04月10日
检验环境条件： （18～25）℃ （30～70）%RH
判定依据： YY/T 0969-2013
检测依据： YY/T 0969-2013等相关方法标准见附页and other method standards refer to next pages

检验结论：

检验结果见附页。
Test result refer to next pages.

林月明　吴燕蕙　　王燕归　李浙

主检：林月明 吴燕蕙　　审核：王燕归 李浙

SMQ-V1.0-007

检 验 报 告

报告编号：WT204017509

检 验 项 目 Test Item	标 准 要 求 Requirement	实 测 结 果 Test Result	单项结论 Conclusion
1.外观 Appearance (YY/T 0969-2013)	4.1条 4.1Requirement	(YY/T 0969-2013) 1#～3#符合Conformity	符合 Conformity
2.结构与尺寸 Structure and size (YY/T 0969-2013)		(YY/T 0969-2013)	符合 Conformity
1).结构Structure	4.2条 4.2Requirement	1#～3#符合Conformity	
2).尺寸Size	4.2条 4.2Requirement	偏差Deviation rate (%) 1# 2# 3# 长度length: -1.7 -0.6 -1.7 宽度width: +2.1 -1.1 +2.1	
3.鼻夹Nose clip (YY/T 0969-2013)		(YY/T 0969-2013)	符合 Conformity
	4.3.1条 4.3.1Requirement 4.3.2条 4.3.2Requirement	1#～3#符合 Conformity 长度length (cm) : 1# 2# 3# 10.2 10.3 10.2	
4.口罩带Mask string (YY/T 0969-2013)		(YY/T 0969-2013)	符合 Conformity
	4.4.1条 4.4.1Requirement 4.4.2条 4.4.2Requirement	符合Conformity 1#～6#:符合Conformity (定负荷Fixed load: 10N, 持续continuous: 5s)	

检 验 报 告

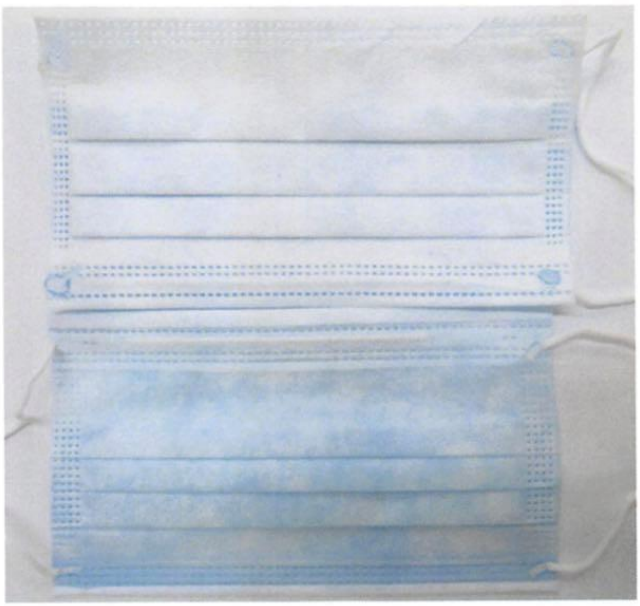
检 验 项 目 Test Item	标 准 要 求 Requirement	实 测 结 果 Test Result	单项结论 Conclusion
5.细菌过滤效率（%） Bacterial filtration efficiency (BFE) (YY/T 0969-2013)	≥95	(YY 0469-2011) 1# 2# 3# 100 100 100	符合 Conformity
6.通气阻力(Pa/cm^2) Ventilation resistance (YY/T 0969-2013)	≤49	(YY/T 0969-2013) 1# 2# 3# 29.6 34.2 38.5 （气体流量Gas flow：8L/min）	符合 Conformity
7.微生物 Microorganisms (YY/T 0969-2013)		(GB 15979-2002)	符合 Conformity
细菌菌落总数（CFU/g） Total amount of bacterial colony	≤100	28	
大肠菌群 Coliform group	不得检出No detected	未检出Not detected	
绿脓杆菌 Pseudomonas aeruginosa	不得检出No detected	未检出Not detected	
金黄色葡萄球菌 Staphylococcus aureus	不得检出No detected	未检出Not detected	
溶血性链球菌 Streptococcus hemolyticus	不得检出No detected	未检出Not detected	
真菌Fungal colony	不得检出No detected	未检出Not detected	

检 验 报 告

附注：

1.此报告以中文为准，英文仅作参考.The Chinese version of this test report is the standard one,the English version is only for reference.

2.样品图片Photo(s) of the sample(s)：



以下空白 END OF REPORT

重要声明
Important statement

1. 本院是深圳市人民政府依法设置的产品质量监督检验机构，系社会公益型非营利性技术机构，为各级政府执法部门进行监督管理提供技术支持和接受社会各界的委托检验。
   SMQ is a legal non-profit technical institute established by Shenzhen Municipal Government to undertake the quality supervision and inspection of products, and to provide technical support to relevant supervision and administration and also conduct commission test from the society.
2. 本院保证检验的科学性、公正性和准确性，对检验的数据负责，并对委托单位所提供的样品和技术资料保密。
   SMQ is committed to assuring the scientificness, impartiality and accuracy of all tests carried out, responsibility for test data gained, and keeping confidential of all test samples and technical documents provided.
3. 抽样按照本院程序文件CX11-01《抽样程序》和相应产品的检验细则的规定执行。
   The sampling should be carried out according to the "sampling procedure" defined in the Procedure Document CX11-01 and relevant testing specifications.
4. 报告无主检、审核、批准人签字，或涂改，或未盖本院“检验检测专用章”及骑缝章无效。未经本院许可，不得部分复印、摘用或篡改本证书/报告内容。
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5. 送样委托检验结果仅对来样有效；委托检验的样品信息及委托方信息均由委托方填写，本院不对其真实性及准确性负责。
   The test results presented in the report apply only to the tested sample. The product information and the applicant information are provided by the customer and SMQ assumes no responsibility for their validity and accuracy.
6. 未经检验机构同意，样品委托人不得擅自使用检验结果进行不当宣传。
   Any use of SMQ test result for advertisement of the tested material or product must be approved in writing by SMQ.
7. 无CMA标志的报告，仅供使用方内部参考，不具有对社会的证明作用。含粤字编号的CAL标志仅适用于产品标准和判定标准。
   The non-CMA report issued by SMQ is only permitted to be used by the client as internal reference use and shall not be used for public demonstration purpose. CAL logo with symbol "Yue" is only relevant to product standards and reference of standards.
8. 对农产品监督抽查检验结果有异议的，可以自收到检验报告之日起五日内，向组织实施农产品质量安全监督抽查的农业行政主管部门或者其上级农业行政主管部门申请复检。对食品监督检验报告有异议的，可以自收到检验报告之日起七个工作日内向实施抽样检验的食品药品监督管理部门或者其上一级食品药品监督管理部门提出复检申请。对其它检验报告有异议的，应于报告发出之日起十五日内向本院提出。
   Any objections to the testing results of supervision sampling of agricultural products should apply for retest within 5 days upon receiving the test report to the administrative department of agriculture who organizes and implements agricultural products' supervision sampling or its superior department. Any objections to the testing results of supervision sampling of food should apply for retest within 7 days upon receiving the test report to the administrative department of food and drug who organizes and implements supervision sampling for food or its superior department. Any objections to other inspection report issued by SMQ should be submitted to SMQ within 15 days after the issuance of the test report.
9. 电子版证书/报告更改后将不被追回，委托方有义务将更改后的报告/证书提供给使用原报告/证书的相关方。
   SMQ is not responsible for recalling the electronic version of the original report/certificate when any revision is made to them. The applicant assumes the responsibility of providing the revised version to any interested party who uses them.

投诉电话：0755-86009898-31206（西丽Xili） 0755-26941613（龙珠 Longzhu）
Complaint hotline: 0755-27528392（龙华 Longhua）

动态更新：取得国外标准认证或注册的医疗物资生产企业清单

2020年05月19日 中国医药保健品进出口商会

取得国外标准认证或注册的医疗物资生产企业清单			
Name List of Medical Devices and Supplies Companies with Certification/Authorization from other Countries 动态更新：2020年5月19日 **下载**			
序号	**生产企业**	**统一社会信用代码**	**国外注册认证情况**
一、	医用口罩 Medical Face Masks		
396	广西三诺智慧健康科技有限公司 Guangxi 3NOD Intelligent Health Technology Co., Ltd	91450500MA5PAXHQ4Y	欧盟CE

统一社会信用代码

91450500MA5PAXHQ4Y

营业执照

扫描二维码登录"国家企业信用信息公示系统"了解更多登记、备案、许可监管信息。

名　　称　广西三诺智慧健康科技有限公司

类　　型　有限责任公司（非自然人投资或控股的法人独资）

法定代表人　张俊超

经营范围　一、二类医疗器械、防护用品的技术开发、生产和销售，自营和代理一般商品和技术的进出口业务。（依法须经批准的项目，经相关部门批准后方可开展经营活动。）

注册资本　叁仟万圆整

成立日期　2020年03月06日

营业期限　长期

住　　所　广西北海市工业园区高科路3号广西三诺智慧产业园区四区2幢3层

登记机关　北海市市场监督管理局园区分局

2020 年 03 月 30 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

国家市场监督管理总局监制

中华人民共和国医疗器械注册证

注册证编号：桂械注准20202140175

注册人名称	广西三诺智慧健康科技有限公司
注册人住所	广西北海市工业园区高科路3号广西三诺智慧产业园区四区2幢3层
生产地址	广西北海市工业园区高科路3号广西三诺智慧产业园区三区2幢3层
代理人名称	不适用
代理人住所	不适用
产品名称	一次性使用医用口罩（非无菌）
型号、规格	长方形 耳挂式 17.5cm×9.5cm
结构及组成	由口罩体、口罩带和鼻夹组成。口罩体至少有三层：内层（纺粘层）、中间层（熔喷层）、外层（纺粘层）。
适用范围	本产品适用于临床各类人员在非有创操作过程中佩戴。用于覆盖住使用者的口、鼻及下颌，为阻隔口腔和鼻腔呼出或喷出污染物的直接透过提供一定的物理屏障。
附　件	产品技术要求
其他内容	
备　注	该证通过应急审批方式办理。

审批部门：广西壮族自治区药品监督管理局　　批准日期：2020年04月23日

有效期至：2021年04月23日

审批部门盖章

资质齐全 安心防护

医疗器械注册证编号：粤深食药监械经营备202026360号

医疗器械注册证编号：桂械注准2020140175号