ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

EC DECLARATION OF CONFORMITY

CE

Manufacturer:	Textile Source Medical Supplies Group Co., Ltd. No.12 Standard workshop, 69 Chang'gang Street, Guangxi ASEAN Economic and Technological Development Zone, China
EC Authorized Representative:	Caretechion GmbH Niederrheinstr. 71, 40474 Duesseldorf, Germany
Registered trade Name or mark:	None

We declare under our sole responsibility that

Name of the Medical device:	Disposable Medical Mask（Type II&IIR） Model：3-ply Protection with Elastic Earloop, 3-ply Tie-On
Product code:	UMDNS code 12447 (masks)
Intended purpose:	The Disposable Medical Mask is intended to be worn to protect against the spread or transmission of infectious germs during surgical interventions in operating theatres and other medical facilities. 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.
Of class:	Rule1, Class I According to annex VIII of Regulation (EU) 2017/745
CS reference:	NONE
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.

Meets the provisions of the Regulation EU 2017/745 which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Name und Funktion / Name and function:
Nom et fonction / Nome e funzione: Chief Executive Officer

Ort, Datum / Place, date:
Lieu, date / Luogo, data: Guangxi 2020.4.5

CE

Ver. A/0

DIMDI - Deutsches Institut für Medizinische Dokumentation und Information

Anzeige

Anzeige

Meldungsnummer	00161645
Formularnummer	00302128
Typ der Anzeige	Erstanzeige Medizinprodukt
Anzeigender nach § 25 MPG	Bevollmächtigter
Datum der Weiterleitung an zuständige Behörde	2020-04-14
Bearbeitungsstatus	weitergeleitet zur Behörde
Bearbeitungsdatum	2020-04-14
Erstellungsdatum	2020-04-14

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	—
Allgemeine Produktbezeichnung	Disposable Medical Mask
Nomenklaturcode	12-447
Nomenklaturbezeichnung	Maske
Kategorie	Produkte zum Einmalgebrauch
Kurzbeschreibung in Deutsch	Die medizinische Einwegmaske soll zum Schutz vor der Ausbreitung oder Übertragung infektiöser Keime bei chirurgischen Eingriffen in Operationssälen und anderen medizinischen Einrichtungen getragen werden. Hauptziel ist es, den Patienten vor infektiösen Keimen zu schützen. Darüber hinaus sollte der Träger in bestimmten Situationen vor Spritzern potenziell kontaminierter Flüssigkeiten und lebensfähiger Partikel geschützt werden.
Kurzbeschreibung in Englisch	The Disposable Medical Mask is intended to be worn to protect against the spread or transmission of infectious germs during surgical interventions in operating theatres and other medical facilities. 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.

1.Hersteller

Bezeichnung	Textile Source Medical Supplies Group Co., Ltd.
Staat	China
Ort	Guangxi
Postleitzahl	530105
Strasse	No.12 Standard workshop, 69 Chang'gang Street, Guangxi ASEAN Economic and Technological Development Zone
Telefon	+86 0771-3901723
Telefax	+86 0771-3901723
E-Mail	273426534@qq.com

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00302128

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 **Textile Source Medical Supplies Group Co., Ltd.**		
	Staat / State **CN**		
	Ort / City **Guangxi**		Postleitzahl / Postal code **530105**
	Straße, Haus-Nr. / Street, house no. **No.12 Standard workshop, 69 Chang'gang Street, Guangxi ASEAN Economic and Technological Development Zone**		
	Telefon / Phone **+86 0771-3901723**		Telefax / Fax **+86 0771-3901723**
	E-Mail / E-mail **273426534@qq.com**		

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

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
Die medizinische Einwegmaske soll zum Schutz vor der Ausbreitung oder Übertragung infektiöser Keime bei chirurgischen Eingriffen in Operationssälen und anderen medizinischen Einrichtungen getragen werden. Hauptziel ist es, den Patienten vor infektiösen Keimen zu schützen. Darüber hinaus sollte der Träger in bestimmten Situationen vor Spritzern potenziell kontaminierter Flüssigkeiten und lebensfähiger Partikel geschützt werden.

Kurzbeschreibung englisch / English short description
The Disposable Medical Mask is intended to be worn to protect against the spread or transmission of infectious germs during surgical interventions in operating theatres and other medical facilities. 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.

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 **2020-04-14**

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

https://portal.dimdi.de/mpi/servlet/FlowController/ShowDocument?userEu=NA&locktest=true&DB=MPAF&uid=20&formInfos=003...

Medizinprodukte - Informationssystem

Übersicht | Medizinprodukte | In-vitro-Diagnostika | Klinische Prüfungen | Adresse | Firmenfusion | Nutzereinstellungen | Kontakt

Tragen alle Medizinprodukte eine CE-Kennzeichnung und werden innerhalb ihrer Zweckbestimmung eingesetzt?	—

Medizinprodukt

Handelsname	—
Allgemeine Produktbezeichnung	Disposable Medical Mask
Nomenklaturcode	12-447
Nomenklaturbezeichnung	Maske
Kategorie	Produkte zum Einmalgebrauch
Kurzbeschreibung in Deutsch	Die medizinische Einwegmaske soll zum Schutz vor der Ausbreitung oder Übertragung infektiöser Keime bei chirurgischen Eingriffen in Operationssälen und anderen medizinischen Einrichtungen getragen werden. Hauptziel ist es, den Patienten vor infektiösen Keimen zu schützen. Darüber hinaus sollte der Träger in bestimmten Situationen vor Spritzern potenziell kontaminierter Flüssigkeiten und lebensfähiger Partikel geschützt werden.
Kurzbeschreibung in Englisch	The Disposable Medical Mask is intended to be worn to protect against the spread or transmission of infectious germs during surgical interventions in operating theatres and other medical facilities. The main ai 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.

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E-Mail	273426534@qq.com

bearbeiten | zurück

SUBJECT	**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	**Textile Source Medical Supplies Group Co., Ltd.**
CLIENT ADDRESS	No.12 Standard workshop, 69 Chang'gang Street, Guangxi ASEAN Economic and Technological Development Zone, China
TEST PERIOD	19-Mar-2020~06-Apr-2020

Prepared By

Bella Xu

(Bella Xu)
Report Drafter

Authorized By

Leo Liu

(Leo Liu)
Authorized Signatory

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

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

Differential pressure of a medical face mask

1.Purpose

The purpose of the test was to measure the differential pressure of a medical face mask.

2.Sample description was given by the client

Disposable Medical Mask
Type: Earloop/175mm*95mm/non-sterile
Manufacture: Textile Source Medical Supplies Group Co., Ltd.

3.References

EN 14683:2019 Annex C

4.Apparatus

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 Each test specimen shall be conditioned at (21±5)°C and (85±5) % relative humidity for the time required to bring them into equilibrium with atmosphere prior to testing.

6. Procedure

6.1 The test specimen is placed across the 2.5 cm diameter orifice(total area 4.9 cm^2) and clamped into place so as to minimize air leaks and that the tested area of the specimen will be in line and across the flow of air.
6.2 The pump is started and the that tested area of the specimen will be in line and across the flow of air.
6.3 The manometers M1 and M2 are read and recorded.
6.4 The procedure described in steps 6.1~6.3 is carried out on 5 different areas of the mask and readings averaged.

7. Calculation

For each test specimen calculate the different pressure ΔP as follows:

$$\Delta P = \frac{(X_{m1}-X_{m2})}{4.9}$$

X_{m1}: is pressure in Pa, manometer M1, mean of 5 test areas, low pressure side of the material;
X_{m2}: is pressure in Pa, manometer M2, mean of 5 test areas, high pressure side of the material;
4.9 is the cm^2 area of the test material;
ΔP is the different pressure per cm^2 of the test material expressed in Pa.

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

8.Test results

Test Items*		Test Results	Test Methods
Differential Pressure Test (Pa/cm²)	1	29.0	EN 14683:2019 Annex C
	2	30.6	
	3	31.3	
	4	30.4	
	5	31.7	

Note: The test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.

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

Synthetic Blood Penetration Test for Masks

1.Purpose

For evaluating the resistance of medical face masks to penetration by a fixed volume of synthetic blood at a high velocity.

2.Sample description was given by the client

Disposable Medical Mask
Type: Earloop/175mm*95mm/non-sterile
Manufacture: Textile Source Medical Supplies Group Co., Ltd.

3.References

EN 14683:2019
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).

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
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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.

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

Table 1 Target weight differences

Fluid Pressure (mmHg)	Weight difference for 1s difference in spurt duration (g)		
	Min.	Target	Max.
80	2.456	2.506	2.556
120	3.002	3.063	3.124
160	3.466	3.537	3.607

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: (ρ is the density of the test fluid.) t = 0.5 + (2 ρ - 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.

Chemical/Microbiology Laboratory:
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7.Test results

Test Items*		Test Results	Test Methods
Penetration of Synthetic Blood Pressure: 120 mmHg (16.0 kPa)	1	None Seen	EN 14683:2019 ISO 22609:2004
	2	None Seen	
	3	None Seen	
	4	None Seen	
	5	None Seen	
	6	None Seen	
	7	None Seen	
	8	penetration	
	9	None Seen	
	10	None Seen	
	11	None Seen	
	12	None Seen	
	13	None Seen	

Note: The test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.

Chemical/Microbiology Laboratory:
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Bacterial Filtration Efficiency (BFE) Test

1. Purpose

For evaluating the Bacterial Filtration Efficiency (BFE) of medical face mask material.

2. Sample description was given by the client

Disposable Medical Mask

Type: Earloop/175mm*95mm/non-sterile

Manufacture: Textile Source Medical Supplies Group Co., Ltd.

3. References

EN 14683:2019 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 throuth 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 in contact with the challenge.
6.6 Repeat the challenge procedure for each test specimen.
6.7 Repeat a positive control afer completion of the sample set.

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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 (35±2)°C for (20~52) 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 manufacturer of Anderson sampler. The filtration efficiency percentages are calculated as follows:

$$BFE(\%)=\frac{C-T}{C} \times 100$$

Where:

C= average plate count total for positive controls

T= plate count total for sample

8. Test results

Test Items*		Test Results	Test Methods
Bacterial Filtration Efficiency (BFE) (%) Staphylococcus aureus ATCC 6538	1	99.5	EN 14683:2019 Annex B
	2	99.0	
	3	99.3	
	4	99.1	
	5	99.1	

Note:

1.Control average: 2027 CFU.

2.Mean particle size:2.8μm.

3.Testing side: outside of specimen.

4.Testing area: 39.5cm².

5.The test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.

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Cleanliness of Microbial (Bioburden) Test for Masks

1. Purpose

For determination of a population of microorganisms .

2. Sample description was given by the client

Disposable Medical Mask

Type: Earloop/175mm*95mm/non-sterile

Manufacture: Textile Source Medical Supplies Group Co., Ltd.

3. References

EN 14683:2019
EN ISO 11737-1:2018

4. Apparatus and materials

4.1 Orbital shaker
4.2 Sterile 500 mL bottle
4.3 Extraction liquid (1 g/L Peptone, 5 g/L NaCl and 2 g/L Tween 20)
4.4 Tryptone soya agar (TSA)
4.5 Sabouraud dextrose agar (SDA) with chloramphenicol
4.6 Filtration equipment
4.7 Sterilized membrane (0.45μm)

5. Test specimen

5.1 As requested by client, take a total of 5 masks.

6. Procedure

6.1 Weight each mask prior testing
6.2 The full mask is aseptically removed from the packaging and placed in a stomacher bag.
6.3 Pour into 100 mL extraction liquid and process 5 min in a stomacher individually by highest speed.
6.4 After this extraction step, 100 mL of the extraction liquid is filtered through a 0.45μm 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 with chloramphenicol for fungi enumeration. Additionally, plate 10 mL, 1 mL and 0.1 mL of the extraction liquid both for TSA and SDA with chloramphenicol.
6.5 The plates are incubated for 3 d at 30℃ and 7 d at 25℃ for TSA and SDA plates respectively.
6.6 The colonies formed on incubation are counted.

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7. Calculation

The total bioburden is expressed by addition of the TSA and SDA counts. Microbial cleanliness is based on the mask weigh, which is the total bioburden per gram tested.

8. Test results

Test Items*		Test results	Test Methods
Microbial cleanliness (CFU/g)	1	4.3	EN 14683:2019 EN ISO 11737-1:2018
	2	2.2	
	3	2.2	
	4	5.5	
	5	8.7	

Note:

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

2. The test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.

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

4.This report replaces report 721653313-4, 721653313-4 is obsolete.

-END OF THE TEST REPORT-

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