EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: /	**Fujian Youxi zhengquan Cloth CO.,LTD** **Chengxiyuan, economic development zone, Youxi County, Fujian Province**
EC Authorized Representative:/	**Caretechion GmbH** **Niederrheinstr 71,40474 Duesseldorf, Germany**

We declare under our sole responsibility that:

Name of the medical device: /	**Disposable surgical mask**
Type: /	**Type IIR**
Product code:/	**UMDNS code 12458 (Masks, Surgical)**
Intended purpose: /	**The Disposable surgical mask is intended to be worn to protect against th e spread or transmission of infectious germs during surgical intervention s in operating theatres and other medical facilities. The main aim is to pr otect the patient against infectious germs. In addition, in certain situatio ns the wearer should be protected against splashes of potentially contam inated liquids and viable particles.**
Basic UDI-DI:/	**NA**
Trade name:/	**None**
of class: /	**Rule1, Class I** according to annex VIII of Regulation (EU) 2017/745 /
CS reference: /	**NONE**
Applicable standards: /	**EN 14683:2019** **EN ISO 10993-5:2009** **EN ISO 10993:10:2013**
Conformity assessment: /	**Declare the conformity of the abovementioned products by issuing this E U Declaration of Conformity after drawing up the technical documentatio n 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(MDR) which apply to it. The declaration is valid in connection with the "final i nspection report" of the device. /

CE

Fujian P.R. May 21th. 2020

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

Zu[illegible] Manager

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

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00305342

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	**10.06.2020**
Registriernummer / Registration number	**DE/CA20/01-Caretechion-106/20**

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

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00305342

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	**Fujian Youxi zhengquan Cloth CO.,LTD**
Staat / State	**CN**
Ort / City	**Youxi**
Postleitzahl / Postal code	**365100**
Straße, Haus-Nr. / Street, house no.	**Chengxiyuan, economic development zone**
Telefon / Phone	**+86 05986390999**
Telefax / Fax	**+86 05986313117**
E-Mail / E-mail	**2640388080@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**

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

Produktbezeichnung / Name of device
Disposable surgical mask

Nomenklaturcode / Nomenclature code
12-458

Nomenklaturbezeichnung / Nomenclature term
Maske, Chirurgie

Kategoriecode / Category code
10

Kategorie / Category
Produkte zum Einmalgebrauch

Kurzbeschreibung deutsch / German short description
Mund-Nase-Schutz, um Patienten zu schützen.

Kurzbeschreibung englisch / English short description
Medical face mask, to protect patient.

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
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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: **Düsseldorf**

Datum / Date: **2020-05-14**

Name: **JIAN WANG**

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
Carolyn Jänsch	**0211 475-5254**

Caretechion

Caretechion GmbH Niederrheinstr. 71, 40474 Düsseldorf

Fujian Youxi zhengquan Cloth CO.,LTD
Chengxiyuan, economic development zone
365100 Youxi, Fujian, P.R. China

Caretechion GmbH
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40474 Düsseldorf
Tel: 0211 30036618
Fax: 0211 30036619
info@caretechion.de

Geschäftsführer:
Jian Wang
Amtsgericht :
Düsseldorf HRB 82833
USt-ID: DE319481632

Certificate of Notification

This is to certify that, in accordance with the Regulation (EU) 2017/745, Caretechion GmbH agrees to as the EU Authorized Representative for:

Fujian Youxi zhengquan Cloth CO.,LTD
Chengxiyuan, economic development zone
365100 Youxi, Fujian, P.R. China

and confirms the submission of the notification of the medical devices

Product Name: Disposable surgical mask
Form Number: 00305342

into the German DIMDI database according to The Act on Medical Devices (Gesetz über Medizinprodukte - MPG) of Germany.

The Manufacturer has provided Caretechion GmbH with the Declaration of Conformity confirming that the aforementioned medical devices fulfill the applicable requirement of the Regulation (EU) 2017/745. In compliance with The Act on Medical Devices (Gesetz über Medizinprodukte - MPG) of Germany, a safety officer has been appointed.

Note: This certificate will automatically be invalid if the notification is rejected by the competent authority or exceeds the service scope or time of the EU Authorized Representative Agreement.

Mit freundlichen Grüßen

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Amtsgericht Düsseldorf HRB 82833
Ust.-ID :DE319481632

Test Report No.: 721654337-7
Report Date: 12 May 2020

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	**Fujian Youxi zhengquan Cloth CO.,LTD**
CLIENT ADDRESS	Chengxiyuan,economic development zone,Youxi County,Fujian Province
TEST PERIOD	17-Apr-2020~02-May-2020

Prepared By

Bella Xu

(Bella Xu)
Report Drafter

Authorized By

(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:
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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	:	Disposable surgical mask
Sample Quantity	:	60 pieces
Specification	:	/
Size	:	175mm x 95mm
Brand Name	:	/

Remark: The above information was provided by applicant.

Summary of Test Results

No.	Test Item	Test Method	Test Standard Type IIR	Judgement
1	Bacterial Filtration Efficiency Test (BFE), %	EN 14683:2019+AC:2019(E) Annex B	≥ 98	Pass
2	Differential Pressure Test (Pa/cm^2)	EN 14683:2019+AC:2019(E) Annex C	< 60	Pass
3	Synthetic Blood Penetration Test (kPa)	ISO 22609:2004	≥ 16.0	Pass
4	Microbial Cleanliness Test (CFU/g)	EN 14683:2019+AC:2019(E) Annex D	≤ 30	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#: 99.9% Specimen 2#: 99.9% Specimen 3#: 99.9% Specimen 4#: 99.9% Specimen 5#: 99.9%
2	Differential Pressure Test	27.0 Pa/cm^2
3	Synthetic Blood Penetration Test	Specimen 1#~32#: None seen
4	Microbial Cleanliness Test	Specimen 1#: <1 CFU/g Specimen 2#: 2 CFU/g Specimen 3#: 3 CFU/g Specimen 4#: <1 CFU/g Specimen 5#: 1 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 : Disposable surgical mask
Specification : /

Sample Receiving Date : 2020-04-17

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	19	45	0	0	0	0	0	0
2	41	78	0	0	0	0	0	0
3	101	131	0	0	0	0	0	0
4	206	256	0	0	0	0	0	0
5	1179	1371	0	0	0	0	0	0
6	739	513	0	0	0	0	0	0
Total (*T*), CFU	2285	2394	<1	<1	<1	<1	<1	<1
Average (C), CFU	$2.3 \times 10^3 = (P_A+P_B) / 2$							
BFE ,%				99.9	99.9	99.9	99.9	99.9
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.							

Chemical/Microbiology Laboratory:
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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
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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 : Disposable surgical mask
Specification : /

Sample Receiving Date : 2020-04-17

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) ºC 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#	27.7	27.0	< 60	Pass
2#	25.6			
3#	27.4			
4#	28.0			
5#	26.5			

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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 : Disposable surgical mask
Specification : /

Sample Receiving Date : 2020-04-17

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 32 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 1s 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
12#	None Seen		Pass
13#	None Seen		Pass
14#	None Seen		Pass
15#	None Seen		Pass
16#	None Seen		Pass
17#	None Seen		Pass
18#	None Seen		Pass
19#	None Seen		Pass
20#	None Seen		Pass
22#	None Seen		Pass
23#	None Seen		Pass
24#	None Seen		Pass
25#	None Seen		Pass
26#	None Seen		Pass
27#	None Seen		Pass
28#	None Seen		Pass
29#	None Seen		Pass
30#	None Seen		Pass
31#	None Seen		Pass
32#	None Seen		Pass

Chemical/Microbiology Laboratory:
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Regional Head Office:
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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 : Disposable surgical mask
Specification : /

Sample Receiving Date : 2020-04-17

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 30°C and 7 days at (20 to 25)°C 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.

Results*:

Specimen	Colonies of the TSA Plate	Colonies of the SDA Plate	Microbial Cleanliness, (CFU/g)	Requirements	Judgement
1#	0	0	<1	EN14683:2019+AC:2019(E) Annex D EN ISO 11737-1:2018 ≤ 30 CFU/g	Pass
2#	0	2	2		
3#	0	3	3		
4#	0	0	<1		
5#	0	1	1		

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:
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No.151 Heng Tong Road Shanghai
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Test Report

Date: 2020-06-02
No.: DY20040402

Summary

The test article, Disposable surgical mask, was evaluated for potential cytotoxic effects. This study was conducted following the guidelines ofISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (2009). A single preparation of the test article was extracted in single strength Minimum Essential Medium at 37°C for 24 hours. The negative control, reagent control, and positive control extracts were similarly extracted. Triplicate monolayers of L-929 mouse fibroblast cells were dosed with each extract and incubated at 37°C in the presence of 5% CO_2 for 24 hours. Following incubation, the monolayers were examined microscopically for abnormal cell morphology and cellular degeneration.

The MEM test extract showed discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth. The test article extract met the requirements of the test since the grade was not greater than 2(Mild).

Authorized Signatory Approval: Tang

Jonathan Tang

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中国认可
国际互认
检测
TESTING
CNAS L3428

Test Report

Date: 2020-06-01
No. : DY20040404

TEST FACILITY

STC (Dongguan)
68 Fumin Nan Road, Dalang,
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TÜV SÜD Certification and Testing (China) Co., Ltd.
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SUPPLIER

Fujian Youxi zhengquan Cloth CO.,LTD
Chengxiyuan,economic development zone,Youxi
County,Fujian Province

CONFIDENTIAL

STUDY TITLE

Guinea Pig Maximization Sensitization Test

TEST ARTICLE NAME

Disposable surgical mask

TEST ARTICLE IDENTIFICATION

CP-MD-2176

CSD No.: CL20200402470

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Chengxiyuan,economic development zone,Youxi County,Fujian Province

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STUDY TITLE

Cytotoxicity Test Elution Method of Disposable surgical mask using ISO 10993-5:2009 Test Methods Test on Extract, Minimal Essential Medium with 10% Fetal Bovine Serum Extract

TEST ARTICLE NAME

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Chengxiyuan,economic development zone,Youxi County,Fujian Province

CONFIDENTIAL

STUDY TITLE

Primary skin irritation Study in Rabbits

TEST ARTICLE NAME

Disposable surgical mask

TEST ARTICLE IDENTIFICATION

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CSD No.: CL20200402470

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