1. Table of Contents (Page 1)

2. Basic Information (Page 2)

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4. European Test & Technical Documentation Review Report (Page 5-9)

5. Registration on DIMDI & Declaration of Conformity (Page 10-11)

6. ISO Production Standards Report (Page 12-19)

7. Manufacturer Qualification Certificate & Export License (Page 20-22)

Disposable Medical Face Mask Inherent-Type IIR Strap-on

Brand: Inherent

Type No.: YX121 (Strap-on)

Performance standard: EN 14683:2019 + AC:2019(E) Annex B /C/D & YY/T 0969-2013, tested by TÜV Rheiland & Intertek

Production standards: ISO 10933-10:2010 & ISO 10993-5:2009, tested by CCIC

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

Material: Two-layer PP Nonwoven fabric and One-layer BFE95 Meltblown fabric (3 layers)

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

Earloop design: Breathable and comfortable for prolonged w earing

Expiration date: 2 years from date of manufacturing

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

Carton measurements: 57 x 39 x 42 cm, G.W. 9.2 KGS.

Stock available: Rotterdam The Netherlands, Frankfurt a/m Germany and Madrid Spain

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SURGICAL TYPE IIR
FACE MASK
Inherent
Non-sterile
50 PCS


Inherent
SURGICAL TYPE IIR
FACE MASK
Non-sterile
50 PCS
Non-sterile


TIE-ON FACE MASK INSTRUCTIONS
Intended use


Hunan EEXI Technology&Service Co.,Ltd.
Shanghai International Holding Corp. GmbH (Europe)
Precautions

P4

Produkte
Products

TÜVRheinland®

Prüfbericht-Nr.: *Test Report No.:*	**60377902 002**	**Auftrags-Nr.** *Order No.:*	**168264746** Seite 1 von 6 *Page 1 of 6*
Kunden-Referenz-Nr.: *Client Reference No.:*	N/A	**Auftragsdatum:** *Order date:*	May 13, 2020
Auftraggeber: *Client:*	**Hunan EEXI Technology & Service Co., Ltd.** No.6, North of Pingtou road, Liuyang Hi-tech industrial development zone, Hunan, China		
Prüfgegenstand: *Test item:*	Surgical Face Mask (non-sterile)		
Bezeichnung / Typ-Nr.: *Identification / Type No.:*	YX011, YX121		
Auftrags-Inhalt: *Order content:*	Type test		
Prüfgrundlage: *Test specification:*	EN 14683:2019+AC:2019 except for clause 5.2.6		
Wareneingangsdatum: *Date of receipt:*	May 25, 2020	See Attachment: Photo documentation for details.	
Prüfmuster-Nr.: *Test sample No.:*	20200522		
Prüfzeitraum: *Testing period:*	N/A		
Ort der Prüfung: *Place of testing:*	N/A		
Prüflaboratorium: *Testing laboratory:*	TÜV Rheinland (Shenzhen) Co., Ltd.		
Prüfergebnis*: *Test result*:*	Pass		

geprüft von / *tested by:*

Lucy Jiang

Jun. 02, 2020 Lucy Jiang / Assistant Project Engineer

kontrolliert von / *reviewed by:*

Angela Chen

Jun. 02, 2020 Angela Chen / Department Manager

Datum / *Date*	Name / Stellung / *Name / Position*	Unterschrift / *Signature*	Datum / *Date*	Name / Stellung / *Name / Position*	Unterschrift / *Signature*

Sonstiges / *Other:*

- The test report consists of EN 14683 test report including this cover page (6 pages) and attachment: Photo documentation (6 pages).
- This report is only valid in conjunction with previous report No. 60377902 001.

Zustand des Prüfgegenstandes bei Anlieferung: *Condition of the test item at delivery:* Prüfmuster vollständig und unbeschädigt / *Test item complete and undamaged*

* Legende:	1 = sehr gut (Pass) = entspricht o.g. Prüfgrundlage(n)	2 = gut (Pass) = entspricht o.g. Prüfgrundlage(n)	3 = befriedigend (Fail) = entspricht nicht o.g. Prüfgrundlage(n)	4 = ausreichend N/A = nicht anwendbar	5 = mangelhaft NT = nicht getestet
Legend:	*1 = very good (Pass) = passed e.m. test specification(s)*	*2 = good (Pass) = passed e.m. test specification(s)*	*3 = satisfactory (Fail) = failed e.m. test specification(s)*	*4 = sufficient N/A = not applicable*	*5 = poor NT = not tested*

Dieser Prüfbericht bezieht sich nur auf das o.g. Prüfmuster und darf ohne Genehmigung der Prüfstelle nicht auszugsweise vervielfältigt werden. Dieser Bericht berechtigt nicht zur Verwendung eines Prüfzeichens.
This test report only relates to the a. m. test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any test mark.

EN 14683:2019+AC: 2019
Medical face masks —
Requirements and test methods

Report Reference No.	:	**60377902 002**
Date of issue	:	**See cover page**
Total number of pages	:	**See cover page**
Testing Laboratory	:	**TÜV Rheinland (Shenzhen) Co., Ltd.**
Address	:	1F East & 2-4F, Cybio Technology Building No.1, No.16 Kejibei 2nd Road, High-Tech Industrial Park North Nanshan District, 518057, Shenzhen, China
Applicant's name	:	**Hunan EEXI Technology & Service Co., Ltd.**
Address	:	No.6, North of Pingtou road, Liuyang Hi-tech industrial development zone, Hunan, China
Test specification:		
Standard	:	EN 14683:2019+AC:2019
Test procedure	:	Type test
Non-standard test method	:	N/A
Test Report Form No.	:	EN 14683:2019+AC:2019_A
Test Report Form Originator	:	TÜV Rh (SZ)
Master TRF	:	2020-03
Test item description	:	Surgical Face Mask (non-sterile)
Trade Mark	:	inherent
Manufacturer	:	Same as the applicant
Model/Type reference	:	YX011, YX121
Classification	:	Type IIR

List of Attachments (including a total number of pages in each attachment):

Attachment – Photo Documentation (6 pages)

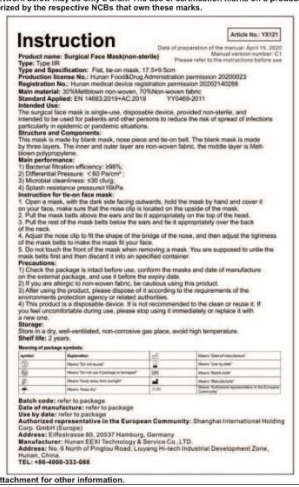
Summary of testing:

Tests performed (name of test and test clause):
Construction check according to:
Clause 5.1.1 Materials and construction
Clause 5.1.2 Design

Testing location:
TÜV Rheinland (Shenzhen) Co., Ltd.
1F East & 2-4F, Cybio Technology Building No.1, No.16 Kejibei 2nd Road, High-Tech Industrial Park North Nanshan District, 518057, Shenzhen, China

Copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.



Instruction

Article No.: YX121

Date of preparation of the manual: April 15, 2020
Manual version number: 01
Please refer to the instructions before use

Product name: Surgical Face Mask(non-sterile)
Type: Type IIR
Type and Specification: Flat, tie-on mask, 17.5×9.5cm
Production license No.: Hunan Food&Drug Administration permission 20200023
Registration No.: Hunan medical device registration permission 20202140288
Main material: 30%Meltblown non-woven, 70%Non-woven fabric
Standard Applied: EN 14683:2019+AC:2019 YY0469-2011
Intended Use:
The surgical face mask is single-use, disposable device, provided non-sterile, and intended to be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations.
Structure and Components:
This mask is made by blank mask, nose piece and tie-on belt. The blank mask is made by three layers. The inner and outer layer are non-woven fabric, the middle layer is Melt-blown polypropylene.
Main performance:
1) Bacterial filtration efficiency: ≥98%;
2) Differential Pressure: <60 Pa/cm² ;
3) Microbial cleanliness: ≤30 cfu/g;
4) Splash resistance pressure≥16kPa
Instruction for tie-on face mask:
1. Open a mask, with the dark side facing outwards, hold the mask by hand and cover it on your face, make sure that the nose clip is located on the upside of the mask.
2. Pull the mask belts above the ears and tie it appropriately on the top of the head.
3. Pull the rest of the mask belts below the ears and tie it appropriately over the back of the neck.
4. Adjust the nose clip to fit the shape of the bridge of the nose, and then adjust the tightness of the mask belts to make the mask fit your face.
5. Do not touch the front of the mask when removing a mask. You are supposed to untie the mask belts first and then discard it into an specified container.
Precautions:
1) Check the package is intact before use, conform the masks and date of manufacture on the outer package, and use it before the expiry date.
2) If you are allergic to non-woven fabric, be cautious using this product.
3) After using the product, please dispose of it according to the requirements of the environmental protection agency or related authorities.
4) This product is a disposable device. It is not recommended to the clean or reuse it. If you feel uncomfortable during use, please stop using it immediately or replace it with a new one.
Storage:
Store in a dry, well-ventilated, non-corrosive gas place, avoid high temperature.
Shelf life: 2 years.
Meaning of package symbols:

symbol	Explanation	symbol	Explanation
	Means "Do not reuse"		Means "Use by date"
	Means "Do not use if package is damaged"		Means "Batch code"
	Means "Keep away from sunlight"		Means "Manufacturer"
	Means "Keep dry"		Means "Authorized representative in the European Community"

Batch code: refer to package
Date of manufacture: refer to package
Use by date: refer to package
Authorized representative in the European Community: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany
Manufacturer: Hunan EEXI Technology & Service Co., LTD.
Address: No. 6 North of Pingtou Road, Liuyang Hi-tech Industrial Development Zone, Hunan, China
TEL: +86-4006-333-088

See attachment for other information.

P5

Testing

Date of receipt of test item(s) ..... : See cover page

Dates of tests performed ..... : See cover page

Possible test case verdicts:

- test case does not apply to the test object ..... : N/A
- test object does meet the requirement ..... : P (Pass)
- test object was not evaluated for the requirement .... : N/E (collateral standards only)
- test object does not meet the requirement ..... : F (Fail)

General remarks:

"(See Attachment #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

Name and address of factory (ies) ..... : Same as the applicant

General product information:

1, This report is only valid in conjunction with previous report No. 60377902 001. Refer to previous test report No. 60377902 001 for more details.
2, The change is to add one model YX121 which is same as previous model YX011 except for manner of wearing, YX121 uses tie-on belts and YX011 uses ear loops.
3, Clause 5.1.1 & 5.1.2 have been checked accordingly, no more test deem necessary after review.

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
5	**Requirements**		**P**
5.1	**General**		**P**
5.1.1	**Materials and construction**		**P**
	The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric.	The Surgical Face Masks are made of blank mask, nose clip and tie-on belts. The outer and inner layers of the mask are made of non-woven fabrics, and the middle layer is made of melt-blown polypropylene.	**P**
	The medical face mask shall not disintegrate, split or tear during intended use.		**P**
	In the selection of the filter and layer materials, attention shall be paid to cleanliness.		**P**
5.1.2	**Design**		**P**
	The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.		**P**
	Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplet(s) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).	With nose clip	**P**
6	**Marking, labelling and packaging**		**P**
	Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied.	See page 4 and attachment.	**P**
	The following information shall be supplied:		**P**
	a) number of this European Standard;		**P**
	b) type of mask (as indicated in Table 1).		**P**
	EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.		**P**

End of EN 14683 test report

Product: Surgical Face Mask (non-sterile)
Type Designation: YX011, YX121

Figure 1 Front / Back view of packaging box (Model: YX121)

Figure 2 Top view of packaging box (Model: YX121)

Product: Surgical Face Mask (non-sterile)
Type Designation: YX011, YX121

Figure 3 Side view of packaging box (Model: YX121)

P6

Figure 4 Side view of packaging box (Model: YX121)

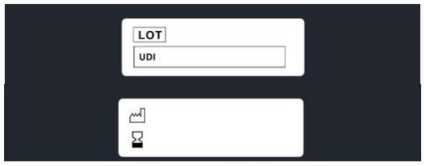


Figure 5 Bottom view of packaging box (Model: YX121)

Figure 6 View of packaging bag (Model: YX121)

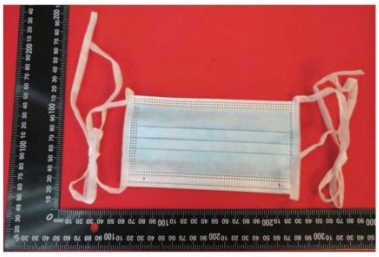


Figure 7 View of face mask (Model: YX121)

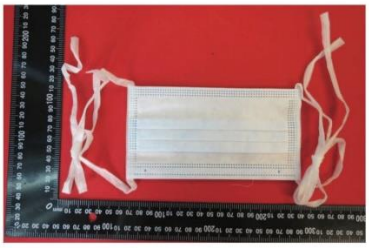


Figure 8 View of face mask (Model: YX121)

Figure 9 View of face mask (3-ply, Model: YX121)

END OF THE PHOTO DOCUMENTATION

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TEST REPORT

Number: GZHT02294303-S1

Report Ref:	GZHT02294303-S1	THIS IS TO SUPERSEDE REPORT NO. GZHT02294303 DATED Jun 03, 2020	
Date Received:	May 19, 2020/May 22, 2020	**Date Issued:**	Jun 09, 2020

Company Name:	HUNAN EEXI TECHNOLOGY & SERVICE CO., LTD
Address:	NO.6, NORTH OF PINGTOU ROAD LIUYANG HI-TECH INDUSTRIAL DEVELOPMENT ZONE, HUNAN CHINA
Contact Name:	徐晓欣

The Following Sample Was Submitted And Identified By/On Behalf Of The Applicant As:

End Uses	: Non-Sterile Medical Face Mask
Ratings	: Type IIR
Sample Name	: Disposable Surgical Mask
Size	: 17.5*9.5cm
Colour	: Blue/white
Standard	: EN 14683:2019+AC:2019
Manufacturer	: HUNAN EEXI TECHNOLOGY & SERVICE CO., LTD
Brand Name	: Inherent
Date received/ Test Started	: May 19, 2020/May 22, 2020
Ref	: Type No.: YX121

Testing was conducted on specific items, at our client's request.

Approved by:

Sr. Manager Assistant Supervisor

QIN / hilaryxu

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch
深圳天祥质量技术服务有限公司广州分公司
Room 02, 1-6/F & Room 01, E101/E201/E301/E401/E501/E601/E701/E801, No.7-2, Caipin Road, Guangzhou Science City, GETDD, Guangzhou, China
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TEST REPORT

Number: GZHT02294303-S1

Original Sample Photo

Approved by:

Sr. Manager Assistant Supervisor

QIN / hilaryxu

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch
深圳天祥质量技术服务有限公司广州分公司
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TEST REPORT

Number: GZHT02294303-S1

Summary of testing:

With reference to following standard:

- EN 14683:2019+AC:2019 Medical face masks – Requirements and test methods Type IIR

Materials Used in The Submitted Sample Were Found To Comply With The Type IIR Requirements of EN 14683:2019+AC:2019 with respect to Microbial Cleanliness, Bacterial Filtration Efficiency, Differential Pressure and Splash Resistance Pressure tests.

Approved by:

Sr. Manager Assistant Supervisor

QIN / hilaryxu

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch
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TEST REPORT

Number: GZHT02294303-S1

Tests Conducted (As Requested By The Applicant)

1 Microbial Cleanliness

As Per EN 14683:2019+AC:2019 Medical face masks-Requirements and test methods Annex D.

Test Item	Result (cfu/g)					Limit (cfu/g)
	Specimen (1)	Specimen (2)	Specimen (3)	Specimen (4)	Specimen (5)	
Microbial cleanliness	<1#	4	3	2	1	Type IIR ≤30

Remark:
cfu = colony forming unit
≤ = Not more than
= No colony was detected at the extraction liquid of the samples.

This Test Item Was Conducted In Caipin Road, Guangzhou Science City, GETDD, Guangzhou, Guangdong.

Sample Received Condition: Sample In Closed Plastic Bag.

QIN / hilaryxu

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch
深圳天祥质量技术服务有限公司广州分公司
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TEST REPORT

Number: GZHT02294303-S1

Tests Conducted (As Requested By The Applicant)

2 Bacterial Filtration Efficiency (BFE)
As Per EN 14683:2019+AC:2019 Medical face masks – Requirements And Test Methods Annex B.

Test Item	Results (%)					Performance Requirement for Medical Face Mask (%)
	Specimen (1)	Specimen (2)	Specimen (3)	Specimen (4)	Specimen (5)	
Bacterial Filtration Efficiency (BFE)	>99.9	99.9	99.8	99.9	99.9	Type IIR: ≥98

Remarks:

1. Biological Aerosol: *Staphylococcus aureus* (ATCC 6538).
2. Testing side: Outside of the test specimen was facing towards the challenge aerosol.
3. Test area: 78 cm^2
4. Flow rate: 28.3 L/min
5. The average plate count results of the positive controls: 1900 CFU
6. The average plate count results of the negative controls: < 1 CFU
7. CFU = Colony Forming Unit

This Item Is Not Under The Testing Scope Of CNAS Accreditation
This Test Item Was Conducted In Caipin Road, Guangzhou Science City, GETDD, Guangzhou, Guangdong.

QIN / hilaryxu

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch
深圳天祥质量技术服务有限公司广州分公司
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TEST REPORT

Number: GZHT02294303-S1

Tests Conducted (As Requested By The Applicant)

3 Splash Resistance Pressure (ISO 22609:2004):

Synthetic Blood Surface Tension: 0.040 N/m, Distance Between Blow Head Front End And Target Area: 300 mm, Artificial Blood Volumes: 2 mL, Test Pressure: 16.0 kPa, Velocity: 550 cm/s, Use A Fixed Target.

Tested Sample	Result	Performance Requirement for Medical Face Mask
Specimen (1)	None seen	Type IIR: No penetration at 16.0 kPa
Specimen (2)	None seen	
Specimen (3)	None seen	
Specimen (4)	None seen	
Specimen (5)	None seen	
Specimen (6)	None seen	
Specimen (7)	None seen	
Specimen (8)	None seen	
Specimen (9)	None seen	
Specimen (10)	None seen	
Specimen (11)	None seen	
Specimen (12)	None seen	
Specimen (13)	None seen	

Remark : 1. Test was conducted by CNTAC Testing Service Co.,Ltd.(Foshan)
2.This Item Is Not Under The Testing Scope Of CNAS Accreditation

QIN / hilaryxu

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch
深圳天祥质量技术服务有限公司广州分公司
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TEST REPORT

Number: GZHT02294303-S1

Tests Conducted (As Requested By The Applicant)

4 Differential Pressure (EN 14683:2019+AC:2019 Annex C):
Air flow: 8L/min, Test area diameter 25 mm, Test area: 4.9 cm^2.

Tested Sample	Result (Pa/cm^2)	Performance Requirement for Medical Face Mask (Pa/cm^2)
Specimen (1)	39.2	Type IIR < 60
Specimen (2)	41.8	
Specimen (3)	36.6	
Specimen (4)	37.2	
Specimen (5)	42.9	
Average	39.5	

Remark : 1. Test was conducted by CNTAC Testing Service Co.,Ltd.(Foshan)
2. This Item Is Not Under The Testing Scope Of CNAS Accreditation

End of Report

QIN / hilaryxu

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch
深圳天祥质量技术服务有限公司广州分公司
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To : HUNAN EEXI TECHNOLOGY & SERVICE CO LTD
Attention : 徐晓晓 Date : Jun 09, 2020

Re : Report Revision Notification

Labtest Report Number GZHT02294303 date JUN 03, 2020

Please be informed that all the content recorded in the above captioned report will be void. This captioned report is now superseded by a revised Labtest Report, Number GZHT02294303-S1 , issued on Jun 09, 2020 .

Thank you for your attention

Approved by:

Sr. Manager Assistant Supervisor

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch
深圳天祥质量技术服务有限公司广州分公司
Room 02, 1-6/F & Room 01, E101/E201/E301/E401/E501/E601/E701/E801, No.7-2, Caipin Road, Guangzhou Science City, GETDD, Guangzhou, China
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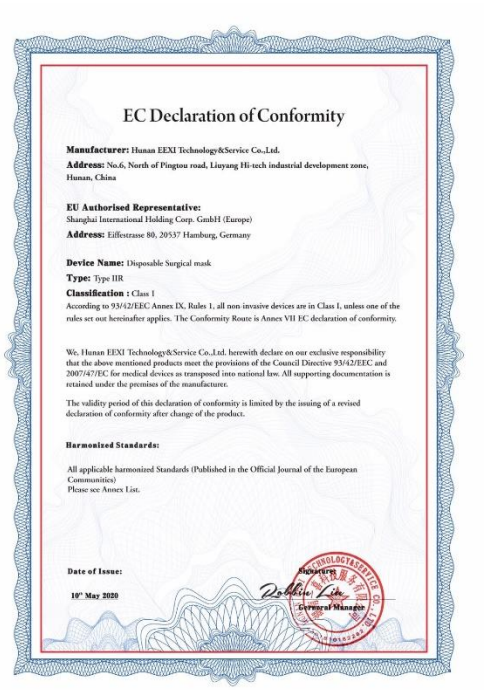


EC Declaration of Conformity

Manufacturer: Hunan EEXI Technology&Service Co.,Ltd.
Address: No.6, North of Pingtou road, Liuyang Hi-tech industrial development zone, Hunan, China

EU Authorised Representative:
Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany

Device Name: Disposable Surgical mask
Type: Type IIR
Classification : Class I
According to 93/42/EEC Annex IX, Rules 1, all non-invasive devices are in Class I, unless one of the rules set out hereinafter applies. The Conformity Route is Annex VII EC declaration of conformity.

We, Hunan EEXI Technology&Service Co.,Ltd. herewith declare on our exclusive responsibility that the above mentioned products meet the provisions of the Council Directive 93/42/EEC and 2007/47/EC for medical devices as transposed into national law. All supporting documentation is retained under the premises of the manufacturer.

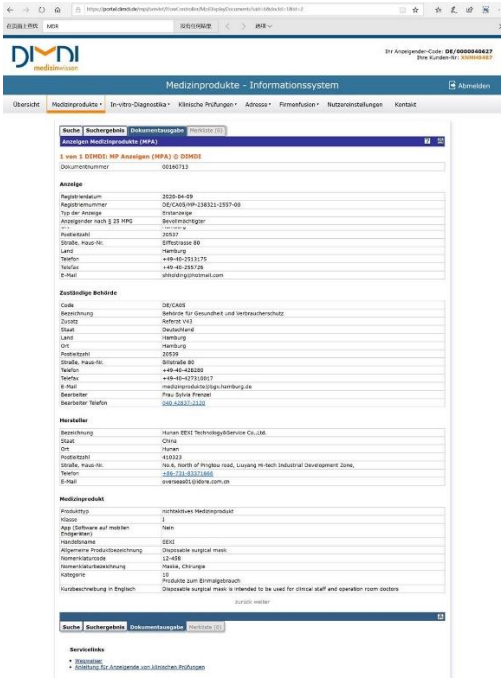
The validity period of this declaration of conformity is limited by the issuing of a revised declaration of conformity after change of the product.

Harmonised Standards:

All applicable harmonized Standards (Published in the Official Journal of the European Communities)
Please see Annex List.

Date of Issue:
10th May 2020

Signature:
Robbie Liu
General Manager



DIMDI medizinwissen

Ihr Anzeigender-Code: **DE/0000040627**
Ihre Kunden-Nr.: 83000040627

Medizinprodukte - Informationssystem

Abmelden

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

Suche | Suchergebnis | Dokumentausgabe | Merkliste (0)

Anzeigen Medizinprodukte (MPA)

1 von 1 DIMDI: MP Anzeigen (MPA) © DIMDI

Dokumentnummer 00160713

Anzeige

Registrierdatum	2020-04-09
Registriernummer	DE/CA05/MP-238321-2557-00
Typ der Anzeige	Erstanzeige
Anzeigender nach § 25 MPG	Bevollmächtigter
Name	[illegible]
Postleitzahl	20537
Straße, Haus-Nr.	Eiffestrasse 80
Land	Hamburg
Telefon	+49-40-2513175
Telefax	+49-40-255726
E-Mail	shholding@hotmail.com

Zuständige Behörde

Code	DE/CA05
Bezeichnung	Behörde für Gesundheit und Verbraucherschutz
Zusatz	Referat V43
Staat	Deutschland
Land	Hamburg
Ort	Hamburg
Postleitzahl	20539
Straße, Haus-Nr.	Billstraße 80
Telefon	+49-40-428280
Telefax	+49-40-427310017
E-Mail	medizinprodukte@bgv.hamburg.de
Bearbeiter	Frau Sylvia Frenzel
Bearbeiter Telefon	040 42827-2120

Hersteller

Bezeichnung	Hunan EEXI Technology&Service Co.,Ltd.
Staat	China
Ort	Hunan
Postleitzahl	410323
Straße, Haus-Nr.	No.6, North of Pingtou road, Liuyang Hi-tech Industrial Development Zone,
Telefon	+86-731-83371666
E-Mail	overseas01@idore.com.cn

Medizinprodukt

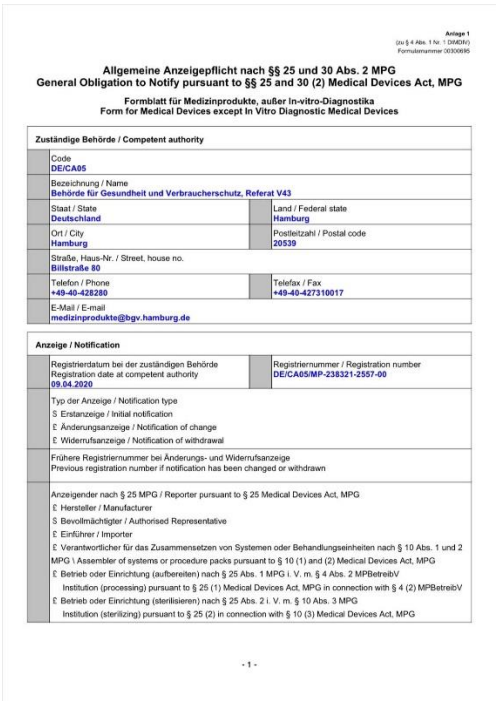
Produkttyp	nichtaktives Medizinprodukt
Klasse	I
App (Software auf mobilen Endgeräten)	Nein
Handelsname	EEXI
Allgemeine Produktbezeichnung	Disposable surgical mask
Nomenklaturcode	12-456
Nomenklaturbezeichnung	Maske, Chirurgie
Kategorie	16 Produkte zum Einmalgebrauch
Kurzbeschreibung in Englisch	Disposable surgical mask is intended to be used for clinical staff and operation room doctors

zurück weiter

Suche | Suchergebnis | Dokumentausgabe | Merkliste (0)

Servicelinks

- Impressum
- Anleitung für Anzeigende von klinischen Prüfungen



Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00300695

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für Medizinprodukte, außer In-vitro-Diagnostika
Form for Medical Devices except In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority

Code
DE/CA05

Bezeichnung / Name
Behörde für Gesundheit und Verbraucherschutz, Referat V43

Staat / State	Land / Federal state
Deutschland	**Hamburg**
Ort / City	Postleitzahl / Postal code
Hamburg	**20539**

Straße, Haus-Nr. / Street, house no.
Billstraße 80

Telefon / Phone	Telefax / Fax
+49-40-428280	**+49-40-427310017**

E-Mail / E-mail
medizinprodukte@bgv.hamburg.de

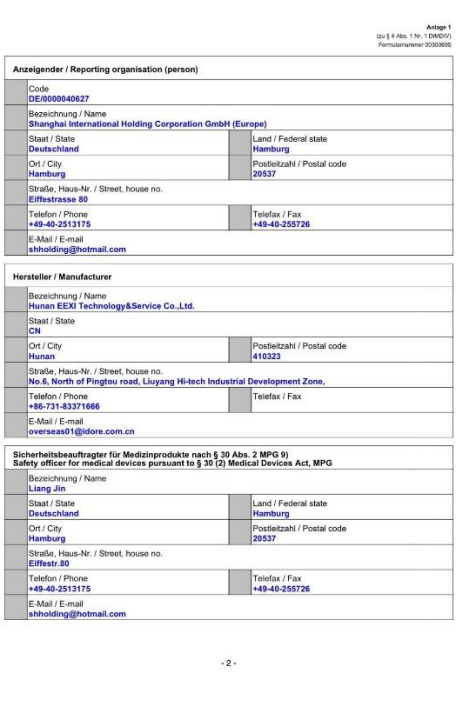
Anzeige / Notification

Registrierdatum bei der zuständigen Behörde Registration date at competent authority	Registriernummer / Registration number
09.04.2020	**DE/CA05/MP-238321-2557-00**

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



Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00300695

Anzeigender / Reporting organisation (person)

Code
DE/0000040627

Bezeichnung / Name
Shanghai International Holding Corporation GmbH (Europe)

Staat / State	Land / Federal state
Deutschland	**Hamburg**
Ort / City	Postleitzahl / Postal code
Hamburg	**20537**

Straße, Haus-Nr. / Street, house no.
Eiffestrasse 80

Telefon / Phone	Telefax / Fax
+49-40-2513175	**+49-40-255726**

E-Mail / E-mail
shholding@hotmail.com

Hersteller / Manufacturer

Bezeichnung / Name
Hunan EEXI Technology&Service Co.,Ltd.

Staat / State
CN

Ort / City	Postleitzahl / Postal code
Hunan	**410323**

Straße, Haus-Nr. / Street, house no.
No.6, North of Pingtou road, Liuyang Hi-tech Industrial Development Zone,

Telefon / Phone	Telefax / Fax
+86-731-83371666	

E-Mail / E-mail
overseas01@idore.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
Liang Jin

Staat / State	Land / Federal state
Deutschland	**Hamburg**
Ort / City	Postleitzahl / Postal code
Hamburg	**20537**

Straße, Haus-Nr. / Street, house no.
Eiffestr.80

Telefon / Phone	Telefax / Fax
+49-40-2513175	**+49-40-255726**

E-Mail / E-mail
shholding@hotmail.com

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00000695

Vertreter / Deputy (optional)

Bezeichnung / Name	
Telefon / Phone	Telefax / Fax
E-Mail / E-mail	

£ Erstanzeige / Initial notification
S Änderungsanzeige / Notification of change

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00000696

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
EEXI

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

Kurzbeschreibung englisch / English short description
Disposable surgical mask is intended to be used for clinical staff and operation room doctors

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00000695

Medizinprodukte (Aufbereiten) / Medical devices (Reprocessing)

£ Semikritische Medizinprodukte / Semicritical medical devices
£ Gruppe A / Group A
£ Gruppe B / Group B

£ Kritische Medizinprodukte / Critical medical devices
£ Gruppe A / Group A
£ Gruppe B / Group B
£ Gruppe C / Group C
Nummer der Bescheinigung / Certificate number

Sterilisationsverfahren / Sterilisation procedures
£ Dampfsterilisation / Steam sterilisation
£ Gassterilisation / Gas sterilisation
£ Strahlensterilisation / Radiation sterilisation
£ andere / others
Angewandtes Verfahren / Applied procedure

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort / City: **Hamburg**
Datum / Date: **2020-03-29**
Name: **Min Fang**
Unterschrift / Signature

Bearbeitungsvermerke / Processing notes
Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority

Bearbeiter / Person responsible **Frau Sylvia Frenzel**	Telefon / Phone **040 42837-2120**

P11

191020340175

中国认可
国际互认
检测
TESTING
CNAS L13034

Skin Sensitization Test

Guinea Pig Maximization

Final Report

Article Name: Disposable medical face mask

Report Number: CSTBB20030201

Method Standard: ISO 10993-10: 2010

Sponsor	Test Facility
Hunan EEXI Technology&Service Co.,Ltd.	CCIC Huatongwei international inspection (Suzhou) Co., Ltd
No.6 north of Pingtou road, Liuyang Hi-tech industrial development zone, Hunan, China	Room 101, Building G, Ruoshui Road 388, Suzhou, Jiangsu, China

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Notices

1. Please apply for rechecking within 15 days of receiving the report if there is any objection.
2. Any erasure or without special testing seal renders the report null and void.
3. The report is only valid when signed by the persons who edited, checked and approved it.
4. The report is only responsible for the test results of the tested samples.
5. The report shall not be reproduced except in full without the written approval of the company.

Abstract

In this study, we took guinea pigs to observe the skin sensitization of the test article according to ISO 10993-10: 2010.

The test article were extracted in Constant Temperature Vibrator at 50 °C, 60 rpm for 72 h by 0.9 % Sodium Chloride Injection and Sesame Oil. Mix 50:50 (by volume) stable emulsion of Freund's complete adjuvant with selected solvent. Intradermal induction and topical induction were operated in the clipped intrascapular region of each animal. After the topical induction phase was completed on day 14, all test and control animals were challenged with the test sample. The erythema and edema of the challenge site were observed to test the sensitization response of the test article. According to the Magnusson and Kligman scales, the response to erythema and edema at each application site of the skin was described and scored 24 hours and 48 hours after the challenge phase.

The results showed that the guinea pigs in the negative control group (0.9 % Sodium Chloride Injection, Sesame Oil) retained a normal appearance throughout the test and showed no skin irritants. A severe skin reactions for erythema and oedema were shown in the positive control group (DNCB). While in test article group, the response of skin on testing side did not exceed that on the control side. The skin reactions for erythema and oedema were not observed in test article group. The data of each group met the acceptance criteria, and the results of this test were considered valid.

Based on the above results, it can be concluded that under the experimental conditions, the test article Disposable medical face mask has no potential skin sensitization on guinea pigs in the extraction method.

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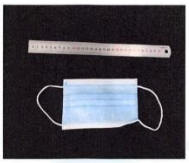
Study Verification and Signature



Protocol Number	SST2003006603BB
Protocol Effective Date	2020-03-13
Technical Initiation Date	2020-03-20
Technical Completion Date	2020-04-17
Final Report Completion Date	2020-04-18

Personnel — Date Completed: 2020-04-18

Approved — Study Director — Date Completed: 2020-04-18

Supervisory — Test Facility Manager — Date Completed: 2020-04-18

Huatongwei international inspection (Suzhou) Co., Ltd.

1.0 Purpose

The test was designed to evaluate the potential of a test article to cause skin sensitization. The test is used as a procedure for screening of contact allergens in guinea pigs and extrapolating the results to humans, but it does not establish the actual risk of sensitization.

2.0 Reference

Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization (ISO 10993-10: 2010)

Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12:2012)

Biological evaluation of medical devices-Part 2: Animal welfare requirements (ISO 10993-2:2006)

3.0 Test and control articles

Groups	Test article	Negative Control Article(Polar)	Negative Control Article(Non-Polar)	Positive Control
Name	Disposable medical face mask	Sodium Chloride Injection (SC)	Sesame Oil (SO)	2, 4-Dinitrochlorobenzene (DNCB)
Manufacture	Hunan EEXI Technology&Service Co.,Ltd.	Shijiazhuang No.4 Pharmaceutical	Jiangxi xinsen natural vegetable oil co., Ltd.	TOKYO CHEMICAL INDUSTRY CO., LTD
Sterilization state	No	/	/	/
Size	17.5cm*9.5cm	500 ml	25 kg	25 g
Model	YX001	/	/	/
Lot Batch#	Not provided	1912121907	181120	H2UKD-DM
Test Article Material	PP non-woven, Melblown filtration layer, earloop and nose clip	/	/	/
Physical State	Solid	Liquid	Liquid	Solid
Color	Not provided	Colorless	Light yellow	Light yellow
Package material	PE poly bag and paper box	/	/	/
Concentration	/	0.9 %	/	Induction Concentration: 0.5 % Challenge Concentration: 1.0 % Dissolved in ethanol
Total	Not provided	/	/	/

Surface/Weight				
Storage Condition	Room Tep.	Room Tep.	Room Tep.	Room Tep.
The information about the test article was supplied by the sponsor wherever applicable.				

4.0 Identification of test system

4.1 Test animal

Species: Hartley Guinea Pig (Cavia Porcellus)

Number: 30 (20 Test +10 Control)

Sex: 15 ♀, 15 ♂

Initial body weight: 301.5~313.5 g

Health status: Healthy, not previously used in other experimental procedures

Animal identification: Ear tag

Cages: Plastic cage

Acclimation Period: 7 days under the same conditions as for the actual test

4.2 Justification of test system

The albino guinea pig has been used historically for sensitization studies (Magnusson and Kligman, 1 970). The guinea pig is believed to be the most sensitive animal model for this type of study. DNCB is the positive control article recommended in the test instructions. To ensure the sensitivity of the experime ntal system, the positive control article should be verified every three months.

5.0 Animal Management

Animal purchase: Wuxi hengtai experimental animal breeding co. LTD SCXK (SU) 2015-0004

Bedding: Corncob Jiangsu Xietong Pharmaceutical Bio-engineering Co., Ltd.

Feed: Guinea pigs were fed with full-price pellets Jiangsu Xietong Pharmaceutical Bio-engineering Co., Ltd.

Water: Drinking water met the Standards for Drinking Water Quality GB 5749-2006

Animal room temperature: 18-26 ℃

Animal room relative humidity: 30 %-70 %

Lights: 12 hours light/dark cycle, full-spectrum lighting

Personnel: Associates involved were appropriately qualified and trained

Selection: Only healthy, previously unused animals were selected

There were no known contaminants present in the feed, water, or bedding expected to interfere with the test data.

6.0 Equipment and reagents

6.1 Instruments

Constant Temperature Vibrator (SHB007, calibration data: 2020/3/16), Autoclave (SHB026, calibration data: 2020/3/16), Electronic scale (SHB017, calibration data: 2020/3/16)

6.2 Reagents

Freund's adjuvant Complete liquid (SIGMA, Lot No: SLBR3877V), Sodium dodecyl sulfate (SDS SIGMA, Lot No: SLBL2304V)

7.0 Experiment design

7.1 Sample preparation

The extracts of test article will be prepared according to the following steps:

Aseptic Sampling			Extraction in sterile vessels				
Sampling Manner	Actually sampling	Ratio	Reagent		Temperature	Time	pH
Whole	570.2 cm^2	6cm^2: 1 ml	SC	95.0 ml	50 ℃	72 h	5.5
	570.2 cm^2		SO	95.0 ml			5.5

Both inducements and excitations were prepared by the number of times. The state of the leaching solution did not change visually after the leaching was advanced. After extraction, the samples were stored at room temperature for no more than 24 h. The extraction solution is clear, and the pH value has not been adjusted, filtered, centrifuged, diluted and other processes. The control solution was prepared under the same conditions.

7.2 Test method

7.2.1 Intradermal induction phasel

A pair of 0.1ml intradermal injections was made for each of the following, into each animal, at the injection sites (A, B and C) as shown in Figure 1 in the clipped intrascapular region.

Site A: A 50:50 (volume ratio) stable emulsion of Freund's complete adjuvant mixed with the chosen solvent.

Site B: The test sample (undiluted extract); the control animals were injected with the solvent alone.

Site C: The test sample at the concentration used at site B, emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the solvent (50 %); the control animals were injected with an emulsion of the blank liquid with adjuvant.

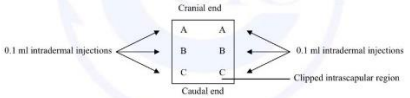


Figure 1 Location of intradermal injection sites

7.2.2 Topical induction phaseII

The maximum concentration that can be achieved in Intradermal induction phase I did not produce irritation, animals are pretreated with 10% sodium dodecyl sulfate 24(±2) hours before the topical induction application.

At 7 d after completion of the intradermal induction phase, administer test article extract by topical application to the intrascapular region of each animal, using a patch of area approximately 8 cm^2 (absorbent gauze), so as to cover the intradermal injection sites. Secure the patches with an occlusive dressing. Remove the dressings and patches after (48±2) h.

Treat the control animals similarly, using the blank liquid alone.

7.2.3 Challenge phase

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At 14d after completion of the topical induction phase, challenge all test and control animals with the test sample. Absorbent gauzes (2.5 cmx2.5 cm) were soaked respectively with test article and control article. Apply the test article extract and control article topically to two sites that were not treated during the induction stage. Secure with an occlusive dressing. Remove the dressings and patches after (24±2) h.

8.0 The results observed

The day after challenge exposure, the patch will be removed and the area cleaned gently with gauze if necessary. The site will be wiped gently with a 0.9 % saline soaked gauze sponge prior to each scoring period. The challenge sites will be observed for signs of irritation and sensitization reaction, as indicated by erythema and edema. If necessary, the fur will be shaved or clipped in advance for the convenience of dermal score.

Daily challenge observation scores will be recorded approximately 24, and 48 hours after patch removal in accordance with the following classification system for skin reactions:

Table 1 Magnusson and Kligman scale

Patch test reaction	Grading scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and/or swelling	3

9.0 Evaluation criteria

Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in control animals.

If grades of 1 or greater are noted in control animals, then the reactions of test animals which exceed the most severe reaction in control animals are presumed to be due to sensitization.

If the response is equivocal, rechallenge is recommended to confirm the results from the first challenge.

The outcome of the test is presented as the frequency of positive challenge results in test and control animals.

10.0 Results of the test

All animals were survived and no abnormal signs were observed during the study.Individual results of dermal scoring for the challenge appear in Table 2.

11.0 Conclusion

The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig. Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor's responsibility.

12.0 Record

All raw data pertaining to this study and a copy of the final report are retained in designated Huatongwei archive.

13.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

Table 2 Guinea pig Sensitization Dermal Reactions

Group		No.	Pretest weigh(g)	Finished weigh(g)	The Challenge patch was removed 24h later		The Challenge patch was removed 48h later		Positive rate
					Erythema	Swelling	Erythema	Swelling	
SC	Test	1	312.8	350.1	0	0	0	0	0%
		2	310.8	349.8	0	0	0	0	
		3	311.7	346.8	0	0	0	0	
		4	311.8	346.5	0	0	0	0	
		5	313.5	350.2	0	0	0	0	
		6	308.2	349.3	0	0	0	0	
		7	310.3	352.1	0	0	0	0	
		8	312.2	350.6	0	0	0	0	
		9	307.9	346.8	0	0	0	0	
		10	311.9	347.9	0	0	0	0	
	Control	11	306.8	346.4	0	0	0	0	–
		12	311.6	351.3	0	0	0	0	
		13	307.1	347.9	0	0	0	0	
		14	311.5	356.1	0	0	0	0	
		15	305.9	349.3	0	0	0	0	
SO	Test	16	301.5	346.6	0	0	0	0	0%
		17	311.9	351.6	0	0	0	0	
		18	307.3	348.6	0	0	0	0	
		19	306.0	344.4	0	0	0	0	
		20	302.2	340.5	0	0	0	0	
		21	307.3	348.1	0	0	0	0	
		22	301.9	344.9	0	0	0	0	
		23	306.8	346.1	0	0	0	0	
		24	312.0	356.1	0	0	0	0	
		25	307.3	348.3	0	0	0	0	
	Control	26	312.3	355.7	0	0	0	0	–
		27	311.6	354.5	0	0	0	0	
		28	309.8	354.0	0	0	0	0	
		29	306.3	347.9	0	0	0	0	
		30	307.4	345.9	0	0	0	0	

Table 3 Positive control

Group	No.	Pretest weigh(g)	Finished weigh(g)	The Challenge patch was removed 24 h later		The Challenge patch was removed 48 h		Positive rate
				Erythem	Swelling	Erythem	Swelling	
Test	1	311.2	351.7	2	0	2	0	100%
	2	315.6	360.2	1	0	1	0	
	3	317.2	352.7	0	0	1	0	
	4	312.8	353.9	1	0	1	0	
	5	306.9	341.1	2	0	2	0	
	6	312.2	350.6	0	0	1	0	
	7	317.1	352.2	1	0	2	0	
	8	306.8	350.0	1	0	1	0	
	9	316.5	348.7	1	0	2	0	
	10	317.6	350.2	2	0	2	0	
Control	11	320.5	364.5	0	0	0	0	–
	12	307.6	350.2	0	0	0	0	
	13	306.9	345.1	0	0	0	0	
	14	310.0	352.3	0	0	0	0	
	15	315.8	346.6	0	0	0	0	

Note：The positive control was CSTBB20010001P1(Finish date：2020-02-07).

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检测
TESTING
CNAS L13034

Skin Irritation Test

Extraction Method

Final Report

Article Name: Disposable medical face mask

Report Number: CSTBB20030203

Method Standard: ISO 10993-10: 2010

Sponsor

Hunan EEXI Technology&Service Co.,Ltd.

No.6 north of Pingtou road, Liuyang Hi-tech industrial development zone, Hunan, China

Test Facility

CCIC Huatongwei international inspection (Suzhou) Co., Ltd

Room 101, Building G, Ruoshui Road 388, Suzhou, Jiangsu, China

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Abstract

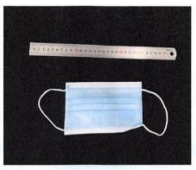
In this study, we took New Zealand white Rabbits to observe the skin irritation of the test article according to ISO10993-10:2010.

The test article were extracted in Constant Temperature Vibrator at 50 ℃, 60 rpm for 72 h by 0.9 % Sodium Chloride Injection and Sesame Oil. Apply 0.5 ml extracts of test article or control to 2.5 cm×2.5 cm absorbent gauze patches, and then apply the patch soaked with the extract of test article or control directly to the skin on each side of each rabbit, and then wrap the application sites with a bandage for a minimum of 4 h. At the end of the contact time, remove the dressing. The describe and score the skin reaction for erythema and oedema for each application site at each time interval. Record the appearance of each application site at (1±0.1) h, (24±2) h, (48±2) h and (72±2) h following removal of the patches.

The results showed that the rabbits in the negative control group (0.9 % Sodium Chloride Injection, Sesame Oil) retained a normal appearance throughout the test and showed no skin irritants. A severe skin reactions for erythema and oedema were shown in the positive control group (SDS). While in test article group, the response of skin on testing side did not exceed that on the control side. The skin reactions for erythema and oedema were not observed in test article group. The data of each group met the acceptance criteria, and the results of this test were considered valid.

Based on the above results, it can be concluded that under the experimental conditions, the test article Disposable medical face mask has no potential skin irritation on rabbit in the extraction method.

Study Verification and Signature



Protocol Number	SST2003006601BB
Protocol Effective Date	2020-03-13
Technical Initiation Date	2020-03-20
Technical Completion Date	2020-03-27
Final Report Completion Date	2020-04-18

Personnel — Date Completed

Approved — Study Director — Date Completed

Supervisory — Test Facility Manager — Date Completed

Huatongwei international inspection (Suzhou) Co., Ltd.

1.0 Purpose

To evaluate the potential skin irritation caused by test article contact with the skin surface of rabbits and extrapolating the results to humans, but it does not establish the actual risk of irritation.

2.0 Reference

Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization (ISO 10993-10: 2010)

Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12:2012)

Biological evaluation of medical devices-Part 2: Animal welfare requirements (ISO 10993-2:2006)

3.0 Test and control articles

Groups	Test article	Negative Control Article(Polar)	Negative Control Article(Non-Polar)	Positive Control
Name	Disposable medical face mask	Sodium Chloride Injection (SC)	Sesame Oil (SO)	10 % sodium dodecyl sulfate (SDS)
Manufacture	Hunan EEXI Technology&Service Co.,Ltd.	Shijiazhuang No.4 Pharmaceutical	Jiangxi xinsen natural vegetable oil co., Ltd.	SIGMA
Sterilization state	No	/	/	/
Size	17.5cm*9.5cm	500 ml	25 kg	25 g
Model	YX001	/	/	/
Lot Batch#	Not provided	1912121907	181120	SLBL2304V
Test Article Material	PP non-woven, Meltblown filtration layer, earloop and nose clip	/	/	/
Physical State	Solid	Liquid	Liquid	Solid
Color	Not provided	Colorless	Light yellow	Colorless
Package material	PE poly bag and paper box	/	/	/
Concentration	/	0.9 %	/	10 %
Total Surface/Weight	Not provided	/	/	/
Storage Condition	Room Tep.	Room Tep.	Room Tep.	Room Tep.
The information about the test article was supplied by the sponsor wherever applicable.				

4.0 Identification of test system

4.1 Test animal

Species: New Zealand white Rabbit

Number: 6

Sex: 3 ♀, 3 ♂

Weight: 2.04~2.17 kg

Health status: Healthy, not previously used in other experimental procedures

Animal identification: Ear tattoo

Cages: Stainless steel cage

Acclimation Period: 7 days under the same conditions as for the actual test

4.2 Justification of test system

The rabbit is specified as an appropriate animal model for evaluating potential skin irritants by the current testing standards. Positive control 10% sodium dodecyl sulfate has been substantiated at HTW with this method.

5.0 Animal Managment

Animal purchase: Wuxi hengtai experimental animal breeding co. LTD SCXK (SU) 2015-0004

Bedding: /

Feed: Experimental rabbits were fed a maintenance diet, Wuxi hengtai experimental animal breeding co. LTD

Water: Drinking water met the Standards for Drinking Water Quality GB 5749-2006

Animal room temperature: 18-26 ℃

Animal room relative humidity: 30 %-70 %

Lights: 12 hours light/dark cycle, full-spectrum lighting

Personnel: Associates involved were appropriately qualified and trained

Selection: Only healthy, previously unused animals were selected

There were no known contaminants present in the feed, water, or bedding expected to interfere with the test data

6.0 Equipment and reagents

6.1 Instruments

Constant Temperature Vibrator (SHB007, calibration data: 2020/3/16), Autoclave (SHB026, calibration data: 2020/3/16), Electronic scale (SHB017, calibration data: 2020/3/16)

7.0 Experiment design

7.1 Sample preparation

The extracts of test article will be prepared according to the following steps:

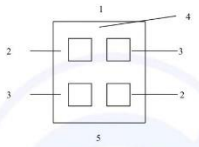
Aseptic Sampling			Extraction in sterile vessels				
Sampling Manner	Actually sampling	Ratio	Reagent		Temperature	Time	pH
Whole	570.2 cm^2	6cm^2: 1 ml	SC	95.0 ml	50 ℃	72 h	5.5
	570.2 cm^2		SO	95.0 ml			5.5

The state of the leaching solution did not change visually after the leaching was advanced. The extractions were clear, and the pH value has not been adjusted, filtered, centrifuged, diluted and other processes, before dosing stored at room temperature no more than 24 h. The control solution was prepared under the same conditions

7.2 Test method

Use the rabbits with healthy intact skin. Fur was generally clipped within 24 h period before testing on the backs of the rabbits, a sufficient distance on both sides of the spine for application and observation of all test sites (approximately 10×15 cm).

Apply 0.5 ml extract (s) of test article or control to 2.5 cm×2.5 cm absorbent gauze patches, and then apply the patch soaked with the extract of test article or control directly to the skin on each side of each rabbit as shown in Figure 1, and then wrap the application sites with a bandage (semi-occlusive or occlusive) for a minimum of 4h. At the end of the contact time, remove the dressing.



1- Cranial end, 2- Test site, 3- Control site, 4- Clipped dorsal region, 5- Caudal end

Figure1 Location of skin application sites

8.0 The results observed

The Describe and score the skin reaction for erythema and oedema according to the scoring system given in Table 1 for each application site at each time interval. Record the appearance of each application site at (1±0.1) h, (24±2) h, (48±2) h and (72±2) h following removal of the patches.

Table 1 Classification System for Skin Reaction

Erythema and Eschar Formation:	Numerical Grading
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet redness) to eschar formation preventing grading of erythema	4
Edema Formation:	
No edema	0
Very slight edema (barely perceptible)	1
Well-defined edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1mm)	3
Severe edema (raised more than 1mm and extending beyond exposure area)	4
Maximal possible score for irritation	8
Irritation Response Categories in the Rabbit	

Response Category	Mean score
Negligible	0 to 0.4
Slight	0.5 to 1.9
Moderate	2 to 4.9
Severe	5 to 8

9.0 Evaluation criteria

Use only (24±2) h, (48±2) h and (72±2) h observations for calculation.

After the 72 h grading, all erythema grades plus oedema grades (24±2) h, (48±2) h and (72±2) h were totalled separately for each test article and blank for each animal. The primary irritation score for an animal was calculated by dividing the sum of all the scores by 6 (two test/observation sites, three time points).

To obtain the primary irritation index for the test article, add all the primary irritation scores of the individual animals and divide by the number of animals.

When blank or negative control was used, calculate the primary irritation score for the controls and subtract that score from the score using the test material to obtain the primary irritation score.

10.0 Results of the test

All animals were survived and no abnormal signs were observed during the study. According to what observed, the response of skin on testing side did not exceed that on the control side. Thus, the primary irritation index for the test article was calculated to be 0. See table 2.

11.0 Conclusion

The test result showed that the response of the test article extract was categorized as negligible under the test condition.

12.0 Record

All raw data pertaining to this study and a copy of the final report are retained in designated Huatongwei archive.

13.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

Table 2 Skin irritation response observation

Reagent	Rabbit No	Pretest weigh(g)	Finished weigh(g)	Group	Reaction	Interval (hours): score=left/right			
						1h	24h	48h	72h
SC	1	2.10	2.18	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
	2	2.09	2.16	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
	3	2.17	2.24	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
Primary irritation index						0			
SO	4	2.04	2.14	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
	5	2.11	2.20	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
	6	2.13	2.21	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
Primary irritation index						0			

Table 3 Positive control

Rabbit No	Group	Reaction	Interval (hours): score=left site/right site			
			1h	24h	48h	72h
1	Positive control	Erythema	0/0	1/2	2/3	3/3
		Oedema	0/0	2/1	2/2	3/3
	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
2	Positive control	Erythema	0/1	2/1	3/3	4/3
		Oedema	1/0	2/2	3/3	3/4
	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
3	Positive control	Erythema	1/0	1/2	3/3	4/3
		Oedema	0/1	2/1	3/4	3/4
	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
Primary irritation index			5.2			

Positive control performed once every six months see CSTBB20020001P3(Finish date：2020-02-21)

191020340175

In Vitro Cytotoxicity Test

MTT Method

Final Report

Article Name: Disposable medical face mask

Report Number: CSTBB20030204

Method Standard: ISO 10993-5：2009

Sponsor

Hunan EEXI Technology&Service Co.,Ltd.

No.6 north of Pingtou road, Liuyang Hi-tech industrial development zone, Hunan, China

Test Facility

CCIC Huatongwei international inspection (Suzhou) Co., Ltd

Room 101, Building G, Ruoshui Road 388, Suzhou, Jiangsu, China

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Abstract

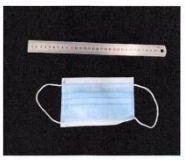
In this study, mammalian L-929 cells were cultured in vitro according to ISO 10993-5:2009 to test the potential cytotoxicity of the test article.

The test articles and the control material were separately placed in MEM medium containing 10% fetal bovine serum, and extracted in a 37 ℃ incubator for 24 hours. After the end of the extraction, the cell culture medium in the 96-well plate (10^4 cells/well) cultured for 24 hours was removed and replaced with the corresponding extract, cultured in 37 ℃, 5% CO_2, >90% humidity for 24 hours. After the culture, the morphology and cell lysis of the cells were observed under the microscope, and the cytotoxicity of the test samples was determined by MTT assay.

The results showed that the cells in the blank control group and the negative control group (high density polyethylene) were well-formed throughout the experiment and showed no cytotoxic reaction. A severe cytotoxic response was shown in the positive control group (ZDEC). The 100% concentration of the test extract retained a normal appearance after 24 hours of incubation, and the cell viability was 78.1%. The data of each group met the acceptance criteria, and the results of this test were valid.

Based on the above results, it can be concluded that under the experimental conditions, the test article Disposable medical face mask have no potential toxicity to L-929 in the MTT method.

Study Verification and Signature



Protocol Number	SST2003006602BB
Protocol Effective Date	2020-03-23
Technical Initiation Date	2020-03-23
Technical Completion Date	2020-03-25
Final Report Completion Date	2020-04-18

Personnel _____ 2020-04-18
Date Completed

Approved _____ 2020-04-18
Study Director Date Completed

Supervisory _____ 2020-04-18
Test Facility Manager Date Completed

Huatongwei international inspection (Suzhou) Co., Ltd.

1.0 Purpose

The purpose of the test is to determine the potential cytotoxicity toxicity of a mammalian cell culture (mouse fibroblast L-929 cells) in response to the test article.

2.0 Reference

Biological evaluation of medical devices-Part 5: Tests for In Vitro Cytotoxicity (ISO 10993-5：2009)

Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12：2012)

3.0 Test and control articles

Groups	Test article	Negative Control Article	Positive Control Article	Blank Control
Name	Disposable medical face mask	High Density Polyethylene Film	ZDEC	MEM medium, with addition 10% FBS
Manufacture	Hunan EEXI Technology&Service Co.,Ltd.	Hatano Research Institute. FDSC	Sigma-Aldrich.	Hyclone
Size	17.5cm*9.5cm	3 cm×10 cm (5 sheets)	25 g	500 ml
Model	YX001	/	/	/
Lot Batch#	Not provided	C-161	BCBQ6847V	AE29441978
Test Article Material	PP non-woven, Meltblown filtration layer, earloop and nose clip	/	/	/
Physical State	Solid	Solid	Solid	Liquid
Color	Not provided	White	White	Pink
Packaging Material	PE poly bag and paper box	/	/	/
Sterilized or Not	No	No	No	Yes
Concentration	/	/	0.1%	/
Total Surface	Not provided	/	/	/
Storage Condition	Room Tep.	Room Tep.	Room Tep.	4℃

Note：The information about the test article was supplied by the sponsor wherever applicable.

4.0 Identification and justification of test system

L-929 mouse fibroblast cells obtained from American Type Culture Collection (ATCC).

L-929 cells have been used for cytotoxicity studies because they demonstrate sensitivity to extractable cytotoxic articles. Also, the test article is extracted and administered in vitro to mouse fibroblast L929 cells through a solvent compatible with the test system, which is the optimal route of administration available in this test system as recommended in ISO 10993-5.

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5.0 Equipment and reagents

5.1 Instruments

Vertical pressure steam sterilizer (SHB026), CO_2 Incubator (SHB002), Steel Straight Scale (SHB076), Electronic Balance (SHB016), Clean bench (SHB014), Multiskan Spectrum Microplate Spectrophotometer (SHB003), Bench type low speed centrifuge (SHB022), Inverted microscope (SHB005)

5.2 Reagents

MEM (Hyclone, AE29441978), FBS (Clark, JC65116), Penicillin-Streptomycin (Gibco, 2145453), Trypsin (Gibco, 2048080), PBS (Hyclone, AE29451445), MTT (3-(4,5-Dimethylthiazol-2-yl)-2,5-diphenyletrazolium bromide) (Sigma, MKBG2038V), Isopropyl alcoho (Macklin, C10394867)

6.0 Experiment design and dose

6.1 Sample preparation

According to the table below, aseptic extraction of the test article sealed and incubated in MEM medium (10% FBS) at 37 ℃, 5% CO_2 and 60 rpm for 24 hours.

Groups	Sampling		Sterilization	Aseptic Extraction In Inert Container				Final Extract
	Sampling Manner	Actually sampling	Method	Ratio	Extracts	Condition	pH	Clear or Not
Test article	Whole	570.2 cm^2	EO	6 cm^2: 1 ml	95.0 ml	37 ℃ 24 h	7.4	Clear
Negative Control	Random	60 cm^2	UV	3 cm^2: 1 ml	20.0 ml	37 ℃ 24 h	7.4	Clear
Positive Control	Random	0.02 g	Filter	0.1 g: 100 ml	20.0 ml	37 ℃ 24 h	7.4	Clear
Blank Control	/	/	/	/	10.0 ml	37 ℃ 24 h	7.4	Clear

The changes of the leaching solution was observed after extraction. No particulates or color changes were observed in pre- and post-extraction, and immediately be used in the follow-up experiment. The color and pH of the extraction solution did not change before and after use, and the pH value was 7.4 after leaching.

6.2 Test method

Aseptic procedures were used for handling cell cultures. L-929 cells were cultured in MEM medium (10% FBS, 1% Penicillin-Streptomycin solution) at 37 ℃ in a humidified atmosphere of 5% CO_2, then digested by 0.25% trypsin containing EDTA to get single cell suspension. 1×10^5 cells/ml suspension were obtained by centrifuging (1000 rpm, 5 min) and re-dispersing in MEM medium.

The suspended cells were dispensed at 100 μl per well in 96-well plate, and cultured in cell incubator (5% CO_2, 37 ℃, >90% humidity). Cell morphology was evaluated to verify that the monolayer was satisfactory.

After the cells grew to about 70% and form a monolayer, original culture medium was discarded. The 96-well plates were then treated with 100 μl of extract of test article (100%、75%、50%、25%), control article, negative article and positive article respectively. The 96-well plate was incubated at 37 ℃ in cell incubator of 5% CO_2 for 24 h. Six replicates of each test were tested.

After incubation, observe the cell morphology first and then discard the culture medium. Add 50 μl MTT (1mg/ml) to each well and then incubated at 37 ℃ in a humidified atmosphere of 5% CO_2 for 2 hours. The liquid in each well was tipped out and 100 μl Isopropyl alcoho was added to each well to suspend the cell layer.

Evaluate the suspension above with a dual-wavelength spectrophotometer with the measurement wavelength at 570 nm.

7.0 Statistical method

Mean±standard deviation ($\bar{x} \pm s$)

The cell cytotoxicity ratio = OD_{570} of test (or positive or negative) article group/ OD_{570} of blank control group×100%.

8.0 Evaluation criteria

8.1 The 50% extract of the test article should have at least the same or a higher viability than the 100% extract. Otherwise the test should be repeated.

8.2 The lower the Viab.% value, the higher the cytotoxic potential of the test article is.

8.3 If viability is reduced to < 70% of the blank, it has a cytotoxic potential.

8.4 The Viab.% of the 100% extract of the test article is the final result.

9.0 Results of the test

9.1 Results of the cell morphology

Table 1 Observation of the cell morphology

Group	Before inoculation	Before treated with extract	24 h after treatment
Blank control	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
Negative control			Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
Positive control			Nearly complete or complete destruction of the cell layers.
100% Test article extract			The cells showed a round shape and a change in cell morphology occasionally, and there were particles in the cytoplasm, occasionally cell lysis and slight growth inhibition.
75% Test article extract			The cells showed a round shape and a change in cell morphology occasionally, and there were particles in the cytoplasm, occasionally cell lysis and slight growth inhibition.
50% Test article extract			The cells showed a round shape and a change in cell morphology occasionally, and there were particles in the cytoplasm, occasionally

			cell lysis and slight growth inhibition.
25% Test article extract			The cells showed a round shape and a change in cell morphology occasionally, and there were particles in the cytoplasm, occasionally cell lysis and slight growth inhibition.

9.2 Results of the cell vitality

Table2 Results of the cell vitality

Group	OD value								Viab. (%)
	1	2	3	4	5	6	$\bar{x}$	s	
Blank control	0.601	0.663	0.638	0.655	0.606	0.629	0.632	0.025	100.0
Negative control	0.598	0.582	0.598	0.599	0.597	0.593	0.595	0.006	94.1
Positive control	0.054	0.062	0.061	0.059	0.068	0.064	0.061	0.005	9.7
100% test article extract	0.489	0.497	0.486	0.495	0.492	0.502	0.494	0.006	78.1
75% test article extract	0.523	0.525	0.535	0.524	0.519	0.508	0.522	0.009	82.6
50% test article extract	0.539	0.538	0.547	0.536	0.535	0.537	0.539	0.004	85.2
25% test article extract	0.549	0.555	0.567	0.589	0.585	0.565	0.568	0.016	89.9

10.0 Conclusion

Under the conditions of this study, the test article have no potential toxicity to L-929 cells.

11.0 Record

All raw data pertaining to this study and a copy of the final report are to be stored in the designated archive files at Huatongwei.

12.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

中国国际贸易促进委员会

China Council for the Promotion of International Trade
China Chamber of International Commerce

证明书
CERTIFICATE

号码 No. 20430080/001493

兹证明：在所附中华人民共和国医疗器械产品出口销售证明上的湖南省药品监督管理局的印章属实。

THIS IS TO CERTIFY THAT: the seal of HUNAN MEDICAL PRODUCTS ADMINISTRATION on the annexed CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS OF THE PEOPLE'S REPUBLIC OF CHINA is genuine.

CCPIT/CCOIC

China Council for the Promotion of International Trade

授权签字：
Authorized Signature: ZHANG XIAOLING

日期：2020年06月17日
(Date: Jun. 17, 2020)

医疗器械生产许可证

许可证编号：湘食药监械生产许20200023号

企业名称：湖南一喜科技服务有限公司

生产地址：湖南浏阳高新技术产业开发区坪头北路6号3栋

法定代表人：赵俊科

生产范围：

企业负责人：刘祥喜

住　　所：湖南浏阳高新技术产业开发区坪头北路6号3栋

发证部门：湖南省药品监督管理局

有效期限：至 2025 年 03 月 07 日

发证日期：2020年 03月 08 日

国家药品监督管理局制

中华人民共和国医疗器械注册证

注册证编号：湘械注准20202140297

注册人名称	湖南一喜科技服务有限公司
注册人住所	湖南浏阳高新技术产业开发区坪头北路6号3栋
生产地址	湖南浏阳高新技术产业开发区坪头北路6号3栋
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）
型号、规格	产品按照面罩形状分为平面形（PM），按照佩戴方式可以分为耳挂式（G）、绑带式（B）或头带（D）式，按照尺寸可以分为A、B、C、D、E、F、G七种规格。
结构及组成	本产品由罩布、鼻夹、口罩带组成。罩布内外层由无纺布，中间层由熔喷布制成，口罩带由非织造布或松紧带制成。鼻夹由可弯折的聚丙烯鼻夹材料制成。该产品非无菌供应。
适用范围	适用于佩戴者在无在体液和喷溅风险的普通医疗环境下的卫生护理。
附 件	产品技术要求
其他内容	
备 注	1. 该产品为应急审批注册，有效期为八个月；2. 该产品在延续/变更注册时应按医疗器械注册管理要求完善相关资料。

审批部门：湖南省药品监督管理局　　批准日期：2020年03月08日

有效期至：2020年11月07日

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号：湘药监械出 20200033 号
Certificate NO.: HNMPA 20200033

产品名称：见附件
Product(s): Attachment

规格型号：见附件
Model: Attachment

产品注册或备案凭证号：见附件
Registration certificate(s): Attachment

生产企业：湖南一喜科技服务有限公司
Manufacturer: Hunan EEXI Technology&Service Co.,Ltd.

生产企业住所：湖南浏阳高新技术产业开发区坪头北路 6 号 3 栋
Address of manufacturer: No.6, North of Pingtou road, Liuyang Hi-tech industrial development zone, Hunan, China

生产许可或备案凭证号：湘食药监械生产许 20200023 号
Manufacturing License(s): Hunan CFDA Production Permit No. 20200023

兹证明上述产品已准许在中国生产和销售。
This is to certify that the above products have been registered to be manufactured and sold in China.

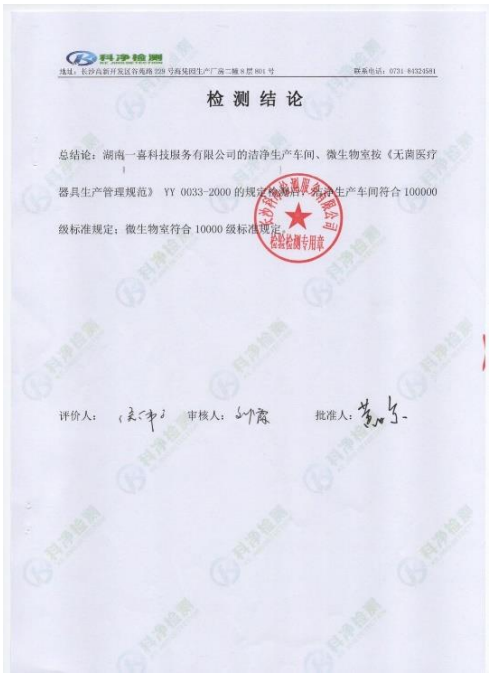
证明有效日期至：2022 年 3 月 19 日
This certification valid until: Mar. 19, 2022

湖南省药品监督管理局
HUNAN MEDICAL PRODUCTS ADMINISTRATION
2020 年 3 月 20 日
Mar. 20, 2020

附件

（Attachment）

序号 No.	产品名称 Product（s）	规格型号 Model	注册证编号 Registration certificate(s)
1	一次性使用医用口罩（非无菌） Disposable medical mask （non-sterile）	规格型号：平面挂耳型。A 11.5cm×7cm, B 12.5cm×9cm, C 17cm×9.5cm, D 17.5cm×9.5cm, E 18cm*9cm, F 18cm×9.5cm, G 14.5cm×9cm Model:Flat mounting ear model. A 11.5cm×7cm, B 12.5cm×9cm, C 17cm×9.5cm, D 17.5cm×9.5cm, E 18cm*9cm, F 18cm×9.5cm, G 14.5cm×9cm	湘械注准：20202140297 Registration certificate(s):Hunan Machinery Registration: 20202140297
2	一次性使用医用口罩（无菌型） Disposable medical face mask （Sterilized）	规格型号：平面挂耳型。A 11.5cm×7cm, B 12.5cm×9cm, C 17cm×9.5cm, D 17.5cm×9.5cm, E 18cm*9cm, F 18cm×9.5cm, G 14.5cm×9cm Model:Flat mounting ear model. A 11.5cm×7cm, B 12.5cm×9cm, C 17cm×9.5cm, D 17.5cm×9.5cm, E 18cm*9cm, F 18cm×9.5cm, G 14.5cm×9cm	湘械注准：20202140289 Registration certificate(s):Hunan Machinery Registration: 20202140289
3	医用外科口罩（无菌型） Surgical mask（Sterilized）	规格型号：平面挂耳型。A 11.5cm×7cm, B 12.5cm×9cm, C 17cm×9.5cm, D 17.5cm×9.5cm, E 18cm*9cm, F 18cm×9.5cm, G 14.5cm×9cm Model:Flat mounting ear model. A 11.5cm×7cm, B 12.5cm×9cm, C 17cm×9.5cm, D 17.5cm×9.5cm, E 18cm*9cm, F 18cm×9.5cm, G 14.5cm×9cm	湘械注准：20202140298 Registration certificate(s):Hunan Machinery Registration: 20202140298
4	医用外科口罩（非无菌） Surgical mask（non-sterile）	规格型号：平面挂耳型。A 11.5cm×7cm, B 12.5cm×9cm, C 17cm×9.5cm, D 17.5cm×9.5cm, E 18cm*9cm, F 18cm×9.5cm, G 14.5cm×9cm Model:Flat mounting ear model. A 11.5cm×7cm, B 12.5cm×9cm, C 17cm×9.5cm, D 17.5cm×9.5cm, E 18cm*9cm, F 18cm×9.5cm, G 14.5cm×9cm	湘械注准：20202140288 Registration certificate(s):Hunan Machinery Registration: 20202140288



科净检测

地址：长沙高新开发区谷苑路359号海关园生产厂房二栋8层801号　　联系电话：0731-84324581

检 测 结 论

总结论：湖南一喜科技服务有限公司的洁净生产车间、微生物室按《无菌医疗器具生产管理规范》 YY 0033-2000 的规定检测结果，洁净生产车间符合 100000 级标准规定；微生物室符合 10000 级标准规定。

评价人：　　审核人：　　批准人：

ISO 9001

认 证 证 书

证书号：USA20Q40924R0M

兹证明

湖南一喜科技服务有限公司

统一社会信用代码：91430181MA4PHUE510

注册地址：湖南浏阳高新技术产业开发区坪头北路6号

生产地址：湖南浏阳高新技术产业开发区坪头北路6号3栋一、二楼

办公地址：湖南浏阳高新技术产业开发区坪头北路6号办公楼

质量管理体系符合标准

ISO 9001:2015

质量管理体系适用范围

一次性使用医用口罩（非无菌型）、一次性使用医用口罩（无菌型）、医用外科口罩（非无菌型）、医用外科口罩（无菌型）的生产（该公司许可证范围内）

初次发证日期　2020年06月20日

证书颁发日期　2020年06月20日

证书换发日期　2020年06月12日

证书有效期至　2023年06月19日

签发：

北京东方纵横认证中心有限公司

EACC　ANAB　IAF

ISO 9001

Certificate

Certificate No.：USA20Q40924R0M

This is to certify that the Quality Management System of

HUNAN EEXI TECHNOLOGY & SERVICE CO., LTD.

Unified Social Credit Code: 91430181MA4PHUE510

Registered/Office Address: No.6 North of Pingtou Road, Liuyang Hi-Tech Industrial Development Zone, Hunan, China

Production Address: Floor 1 and 2, Building 3, No.6 North of Pingtou Road, Liuyang Hi-Tech Industrial Development Zone, Hunan, China

Has been audited to conform to the following Quality Management System standard

ISO 9001:2015

This Quality Management System is valid for the

The production of disposable medical masks (non-sterile), disposable medical masks (sterile), medical surgical masks (non-sterile) and medical surgical masks (sterile) (within the company's license scope)

Date of initial issuance: Apr. 20, 2020

Date of issuance: Apr. 20, 2020

Date of renewal: May. 12, 2020

Date of expiry: Apr. 19, 2023

Issued by:

Beijing East Allreach Certification Center Co., Ltd.

EACC　ANAB　IAF

认证证书

证书号：USA20E40925R0M

兹证明

湖南一喜科技服务有限公司

统一社会信用代码：91430181MA4PHUE510

注册地址：湖南浏阳高新技术产业开发区坪头北路6号

生产地址：湖南浏阳高新技术产业开发区坪头北路6号3栋一、二楼

办公地址：湖南浏阳高新技术产业开发区坪头北路6号办公楼

环境管理体系符合标准

ISO 14001:2015

环境管理体系适用范围

一次性使用医用口罩（非无菌型）、一次性使用医用口罩（无菌型）、医用外科口罩（非无菌型）、医用外科口罩（无菌型）的生产（该公司许可证范围内）及其所涉及场所的相关环境管理活动

初次发证日期 2020年04月20日

证书颁发日期 2020年04月20日

证书换发日期 2020年05月12日

证书有效期至 2023年04月19日

签发：吴凤茹

北京东方纵横认证中心有限公司

Certificate

Certificate No.: USA20E40925R0M

This is to certify that the Environmental Management System of

HUNAN EEXI TECHNOLOGY & SERVICE CO., LTD.

Unified Social Credit Code: 91430181MA4PHUE510

Registered/Office Address: No.6 North of Pingtou Road, Liuyang Hi-Tech Industrial Development Zone, Hunan, China

Production Address: Floor 1 and 2, Building 3, No.6 North of Pingtou Road, Liuyang Hi-Tech Industrial Development Zone, Hunan, China

Has been audited to conform to the following Environmental Management System standard

ISO 14001:2015

This Environmental Management System is valid for the

The production of disposable medical masks (non-sterile), disposable medical masks (sterile), medical surgical masks (non-sterile) and medical surgical masks (sterile) (within the company's license scope) and related environmental management activities of involved sites

Date of initial issuance: Apr. 20, 2020

Date of issuance: Apr. 20, 2020

Date of renewal: May. 12, 2020

Date of expiry: Apr. 19, 2023

Issued by:

Beijing East Allreach Certification Center Co., Ltd.