HYGISUN®

REF HS0602R

Medical Face Mask For Kid

Earloop. Blue

EN14683: 2019+AC: 2019 Type IIR

CARTON DIMENSION (Type IIR - Blue - 5 Farbige * 10er Packung)

HYGISUN®

10 PC/OPP	50 PCS/box	2000 PCS/carton	40000 PCS/pallet

EAN BOX: 4260676530362 EAN OPP: 4260676530379

CE


HYGISUN®
Medical Face Mask For Kid (Non-Sterile)
EARLOOP, BLUE, 145mmX95mm
Classified as Type IIR. Filtration efficiency (BFE) = >98%
ERSTE LAGE UNGEWOBENER STOFF
MITTLERE LAGE FILTERPAPIER (SCHMELZGEBLASENER STOFF)
DRITTE LAGE UNGEWOBENER STOFF
50 PCS
NON STERILE
LATEX
CE EN 14683: 2019+AC: 2019
REF HS0602A
10ER*5BAG
50 Stk.

Gebrauchsanleitung
Instructions for use

Gebrauchsbestimmung / Intend use

Die Masken dienen als Schutzbarriere in einer nicht sterilen Umgebung der Gesundheitsvorsorge.
The masks are used to provide barrier protection in non-sterile healthcare environment.

Struktur und Material / Structure and Material

ungewobener PP Stoff (Innen- und Außenlage) mit Filterstoff (Mittellage), hitzegeformt.
PP Non-Woven fabric(Inner and outer layers) with filter fabric(Middle Layer) heat formed.

⚠ Vorsichtsmaßnahmen / Cautions

1. Überprüfen Sie die Vollständigkeit der Packung vor dem Gebrauch. Prüfen Sie das Label, Herstellungsdatum und die Haltbarkeitszeit um sicherzugehen, dass das Produkt innerhalb seiner Haltbarkeitszeit verwendet wird.
2. Nicht benutzen, wenn die Verpackung beschädigt ist.
3. Nicht wiederverwenden. Die Wiederverwendung kann zu Kreuzkontaminationen führen.

1. Check the package completeness before using. Check the label, manufacturing date and validity time, to make sure the product is in valid date.
2. Do not use if the package damaged.
3. Do not reuse. Reusing may cause cross-contamination.

Lagerung / Storage

Das Produkt sollte in einer kühlen und trockenen Umgebung aufbewahrt werden, fern von Hitze und direkter Sonneneinstrahlung.
The product should be stored in a cool dry area, away from heat and direct sunlight.

Anleitung / How to wear

Ohrschlaufen über beide Ohren hängen.
Ear strap on both ears.

Unterer Teil über das Kinn ziehen.
Pull down mask to cover jaw.

Nasenclip an die Nase form anpassen.
Press down around nose.


HYGISUN®
CE EN 14683: 2019+AC: 2019
Medizinische Gesichtsmaske für Kinder (Nicht steril)
REF HS0602A
10ER*5BAG
OHRSCHLAUFE, BLAU, 145mmX95mm
Als Typ IIR klassifiziert; Filtrationseffizienz (BFE) = > 98%
[EN] Medical face mask
[FR] Masque facial médical
[NL] Medisch gezichtsmasker
[IT] Mascherina medica
[ES] Mascarilla médical
[PT] Máscara facial médica
[SE] Medicinsk ansiktsmask
[DK] Medicinsk ansiktsmaske
[NO] Medicinsk ansiktsmaske
[HU] Orvosi arcmaszk
[CS] Lékařská obličejová maska
[HR] Medicinska maska za lice
50 Stk.
NON STERILE
LATEX


Symbol
Bedeutung / Introductions
Symbol
Bedeutung / Introductions
Nicht verwenden, wenn Verpackung defekt ist
Don't use when packing damaged
"Nicht wiederverwenden" oder "Zur Einmal benutzung"
"Don't reuse" or "Single use"
Warnungen und Vorsichtsmaßnahmen
Warnings and Precautions
Nicht steril
Non-sterile
Name und Adresse des Herstellers
Manufacturer Name Address
Herstellungsdatum
Manufacture Date
Ohne Latex
Latex free
EC REP
Informationen des Vertreters der EU
Information of European Union Representative
LOT
Los-Code
Batch Code
Haltbarkeit
Shelf life
Gebrauchsanleitung beachten
Consult instructions for use
Sichuan Ai Doctor Medical Technology Co.,Ltd.
333 Yongke Road,Yongsheng Town,Wenjiang District,Chengdu Sichuan,China
IMPORTEUR
Sunbeam International GmbH
Schumanstr. 12 52146, Würselen,Germany
EC REP
SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam,Netherlands
4 260676 530362
LOT
A20210305
2021.03.05
2023.03.04
Hergestellt in China
Rev. S/21
Rev. Date: 2021.02.12


Medizinische Gesichtsmaske Für Kinder (Nicht steril)
Als Typ IIR klassifiziert; Filtrationseffizienz (BFE) =>98%
REF HS0602A
10ER*5BAG
HYGISUN®
Medical Face Mask For Kid (Non-Sterile)
Classified as Type IIR. Filtration efficiency (BFE) =>98%
50 Stk.
EARLOOP , BLUE, 145mmX95mm
50 PCS
CE EN 14683: 2019+AC: 2019


HYGISUN®
CE EN14683: 2019+AC: 2019 TYPE IIR
Medizinische Gesichtsmaske für Kinder (Nicht steril)
OHRSCHLAUFE, BLAU, 145mm*95mm
Als Typ IIR klassifiziert; Filtrationseffizienz (BFE)=>98%
Anzahl der Packstücke: 10
[Produktname] HYGISUN Medizinische Gesichtsmaske für Kinder
[Modellspezifikation] Ohrschlaufen; blau; 145mmx95mm; nicht steril.
[Materialien] 70% Vliesstoffe, 30% schmelzgeblasene Vliesstoffe.
[Lagermethode] Masken sind in einem sauberen, belüfteten und trockenen aufzubewahren.
[Vorsichtsmaßnahmen] Es wird empfohlen, es alle 2-4 Stunden auszutauschen. Sobald es kontaminiert ist, sollte es so bald wie möglich ersetzt werden.
REF HS0602A
(10ER PACKUNG)
4 260676 530379
OPEN
Sichuan Ai Doctor Medical Technology Co., Ltd.
333 Yongke Road, Yongsheng town, Wenjiang District,
Chengdu City, Sichuan Province, China
EC REP
SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam,
Netherlands
LOT A20210305
2021.03.05
2023.03.04

Gebrauchsanleitung

CE

[Gebrauchsbestimmung] Die Masken dienen als Schutzbarriere in einer nicht sterilen Umgebung der Gesundheitsvorsorge.
[Struktur und Material] ungewobener PP Stoff (Innen- und Außenlage) mit Filterstoff (Mittellage), hitzegeformt.
[Vorsichtsmaßnahmen]

1. Überprüfen Sie die Vollständigkeit der Packung vor dem Gebrauch. Prüfen Sie das Label, Herstellungsdatum und die Haltbarkeitszeit um sicherzugehen, dass das Produkt innerhalb seiner Haltbarkeitszeit verwendet wird.
2. Nicht benutzen, wenn die Verpackung beschädigt ist.
3. Nicht wiederverwenden. Die Wiederverwendung kann zu Kreuzkontaminationen führen.

[Lagerung] Das Produkt sollte in einer kühlen und trockenen Umgebung aufbewahrt werden, fern von Hitze und direkter Sonneneinstrahlung.

OPEN

Anleitung

Ohrschlaufen über beide Ohren hängen. | Nasenclip an die Nasenform anpassen. | Unteren Teil über das Kinn ziehen.

Symbol	Bedeutung	Symbol	Bedeutung
	Nicht verwenden, wenn Verpackung defekt ist		"Nicht wiederverwenden" oder "Zur Einmalbenutzung"
	Ohne Latex		Nicht steril
	Name und Adresse des Herstellers	EC REP	Informationen des Vertreters der EU
LOT	Los-Code		Herstellungsdatum
	Haltbarkeit		Vor direktem Sonnenlicht schützen
	Gebrauchsanleitung beachten		Trocken aufbewahren

HYGISUN® EN14683:2019+AC:2019 TYPE IIR

HYGISUN®

HYGISUN®

HYGISUN®
Medical Face Mask for Kid

Name: HYGISUN® Medical Face Mask for Kid

Model Specification: Earloop, Blue, 145mmX95mm, Non-Sterile.

Intended Use: The Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These Medical Face Masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.

Cautions:

1. Check the package completeness before using. Check the label, manufacturing date and validity time, to make sure the product is in valid date.
2. Do not use if the package is damaged.
3. Do not reuse. Reusing may cause cross-contamination.

Instruction for use:

1. Open the packaging pouch and take out the mask.
2. Place the side with nose piece upward. Hang the ear loops on the ears.
3. Press the nose piece to fit the bridge of the nose, then press the nose piece and pull the lower end of the mask to the lower jaw.
4. Adjust the mask so that it covers the bridge of the nose to the lower jaw in order to get the best protection effect.

Storage:

The product should be stored in a cool dry place, away from heat and direct sunlight.

Shelf life: 2 Years

Manufacturer Information

Name: Sichuan Ai Doctor Medical Technology Co., Ltd.
Address: 333 Yongke Road, Yongsheng Town, Wenjiang District, Chengdu, Sichuan, China

EC REP
Name: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

IMPORTUER
Name: Sunbeam International GmbH
Address: Schumanstr. 12 52146, Würselen, Germany

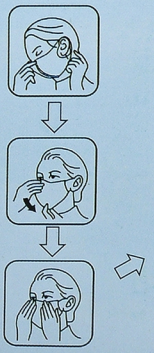
HYGISUN®
www.hygisun.de

SUNBEAM INTERNATIONAL GMBH

Rev. S/ 21 Rev. Date: 2021.02.12

Symbols meaning:

Symbol	Introducions	Symbol	Introducions
LOT	Batch-Code		Do not reuse/ single use/ Use only once
	Don't use when packing is damaged.		Manufacture Date
	Manufacturer Name and address	EC REP	Name and Address of European Union Representative
	Latex free		Shelf life
	Consult instructions for use	IMPORTUER	Importer information
	Warnings and Precautions	NON STERILE	Non-sterile




HYGISUN®
Medical Face Mask For Kid
(Non-Sterile)
EARLOOP, BLUE, 145mmX95mm
Classified as Type IIR. Filtration efficiency (BFE)=>98%
ERSTE LAGE
MITTLERE LAGE
DRITTE LAGE
50 PCS
EN 14683: 2019+AC: 2019
REF HS0602A
10ER*5BAG
Doc No: HS0602A-KID-CE-02
Medical Face Mask For Kid
Medizinische Gesichtsmaske für Kinder
(Nicht steril)
Anzahl der Packstücke: 10
EN14683: 2019+AC:2019 TYPE IIR

510mm X 346mm X 388mm

Medical Face Mask For Kid REF: HS0602A

Rev. S/21-1.0 Rev. Date 2021.02.12

HYGISUN®

Medizinische Gesichtsmaske für Kinder

(NICHT STERIL)

REF HS0602R (10ER*5BAG)

OPP BAG EAN

4 260676 530379

BOX EAN

4 260676 530362

CE

EN14683: 2019+AC: 2019 TYPE IIR

Hergestellt in China

Mass/Dimensions: 510mm X 346mm X 388mm

Menge: 40 Packungen (50Stk./Packung)

Quantity: 40 Box (50pcs/box)

IMPORTEUR Sunbeam International GmbH
Schumanstr. 12 52146, Würselen, Germany

Sichuan Ai Doctor Medical Technology Co., Ltd.
333 Yongke Road, Yongsheng town, Wenjiang District, Chengdu, Sichuan, China

EC REP SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

HYGISUN®

MEDICAL FACE MASK FOR KID

(NON-STERILE)

REF HS0602R (10ER*5BAG)

OPP BAG EAN

4 260676 530379

BOX EAN

4 260676 530362

CE

EN14683: 2019+AC: 2019 TYPE IIR

Made in China

Mass/Dimensions: 510mm X 346mm X 388mm

Menge: 40 Packungen (50Stk./Packung)

Quantity: 40 Box (50pcs/box)

IMPORTEUR Sunbeam International GmbH
Schumanstr. 12 52146, Würselen, Germany

Sichuan Ai Doctor Medical Technology Co., Ltd.
333 Yongke Road, Yongsheng town, Wenjiang District, Chengdu, Sichuan, China

EC REP SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

取得国外标准认证或注册的医疗物资生产企业清单

Name List of Medical Devices and Supplies Companies with Certification/Authorization from other Countries

序号	生产企业	统一社会信用代码	国外注册认证情况
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	四川艾医生医疗科技有限公司 Sichuan Ai Doctor Medical Technology Co.,Ltd.	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Manufacturer

Name: SICHUAN AI DOCTOR MEDICAL TECHNOLOGY CO., LTD.
Address: 333 Yongke Road, Yongsheng Town, Wenjiang District, Chengdu City, Sichuan Province, China

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2019
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 14683:2019+AC:2019 TYPE IIR

Remark
The declaration of conformity is valid in connection with the release technical document XXXX.
All the supporting documentation is retained at the premises of the manufacturer.
The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Product Information

Name: MEDICAL FACE MASK
Model: HS0602A (145*95mm)
GMDN: 35177
Basic UDI-DI:
Classification: Class I
Rule: Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: Date: March 15, 2021

Position:General Manager Place:Hefei /China

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo global service

Authorized Signature (S)

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

SUNGO Europe B.V.
T.a.v. de heer R. Luo
Olympisch Stadion 24
1076 DE Amsterdam

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen via:
medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20211347

Bijlagen
-

Uw aanvraag
15 maart 2021

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 19 maart 2021
Betreft: notificatie medisch hulpmiddel klasse I

Geachte heer Luo,

Hierbij bevestig ik de ontvangst op 15 maart 2021 van de notificatie van het medische hulpmiddel klasse I, dat bedrijf Sichuan Ai Doctor Medical Technology Co., Ltd., met Europees gemachtigde SUNGO Europe B.V., als fabrikant overeenkomstig Verordening (EU) 2017/745 (MDR) op de markt wenst te gaan brengen.
Het product is onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie over dit product het bijbehorende kenmerk te vermelden en het bij telefoongesprekken bij de hand te houden.

Medical Face Mask
(geen merknaam) (NL-CA002-2021-56817)

Ik wijs u erop dat medische hulpmiddelen die op de markt gebracht worden volgens de MDR over een systeem voor hulpmiddelindicatie (UDI) moeten beschikken[1] en dat fabrikanten, gemachtigden en importeurs in de Europese databank voor Europese hulpmiddelen (Eudamed) moeten worden geregistreerd[2].
Bijlage VI van de MDR bevat de bij de registratie te verstrekken gegevens.
Op dit moment is Eudamed nog niet in gebruik, zodat het wat betreft het bovenstaande voldoende is dat u uw product overeenkomstig de huidige wet- en regelgeving hebt genotificeerd.

Zodra Eudamed volledig in gebruik is, wordt de fabrikant of diens gemachtigde geacht binnen achttien maanden bovenstaand hulpmiddel te registreren in Eudamed.[3]

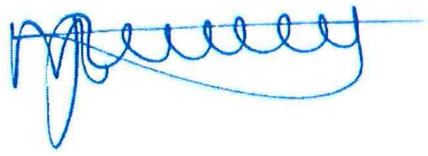
---

[1] O.g.v. art. 29 MDR.
[2] O.g.v. art. 31 MDR.
[3] www.camd-europe.eu/wp-content/uploads/2018/05/FAQ_MDR_180117_V1.0-1.pdf. Zie vraag en antwoord nummer 20.

Tevens wijs ik u er voor de goede orde nog op dat de registratie van uw mededeling betreffende de aflevering van het bovengenoemde product slechts een administratieve handeling betreft. Deze ontvangstbevestiging behelst dan ook geen besluit betreffende de kwalificatie van het desbetreffende product als medisch hulpmiddel in de zin van art. 1 WMH, noch betreffende de indeling in risicoklasse I.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec



Dr. M.J. van de Velde

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

NOTIS

> My cases
> Notify medical devices
> Change products
> Apply for certificate of free sale
> Find products

Notify Class I medical devices

General data

NOTIS number	20211347
Date of receipt	3/15/2021
Status	Finalised
Date finalised	3/24/2021

Client details

Name	SUNGO Europe B.V.
Contact person concerning this notification	Luo, dhr. R.

Manufacturer details

Authorised representative of manufacturer	Sichuan Ai Doctor Medical Technology Co., Ltd.
Address	No.333,Yongke Road, Yongsheng Town, Chengdu Cross-strait Science and Technology Industrial Development Park, Wenjiang District
Zipcode	611130
City	Chengdu, Sichuan
Country	CHINA

Products

Brand name *	Group name	Article number(s)	Model(s)	Class	Status
	Medical Face Mask			MDR I	BEV

Documents

Date	File	Title
3/24/2021	20211347-0005.pdf	20211347
3/24/2021	20211347-0004.pdf	MDR Klasse I Bevestiging AR 1 product
3/15/2021	20211347-0001.pdf	Declaration of Conformity
3/15/2021	20211347-0002.docx	Product information

Print Ok

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	**Sichuan Ai Doctor Medical Technology Co., Ltd.**
CLIENT ADDRESS	333 Yongke Road, Yongsheng Town, Wenjiang District, Chengdu City, Sichuan Province, China.
TEST PERIOD	20-Mar-2021~28-Mar-2021

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

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

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

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

TEST REPORT

Sample Description	:	Medical Face Mask for Kid
Sample Quantity	:	60 pieces
Lot Number/Batch Code	:	A20210305
Specification	:	/
Size	:	/
Brand Name	:	/
Style Number	:	HS0602A

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	Splash Resistance Pressure Test (kPa)	EN 14683:2019+AC:2019(E) 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#: 99.8% Specimen 3#: 99.9% Specimen 4#: 99.9% Specimen 5#: 99.9%
2	Differential Pressure Test	31.8 Pa/cm^2
3	Splash Resistance Pressure Test	Specimen 1#~32#: None seen
4	Microbial Cleanliness Test	Specimen 1#: <1 CFU/g Specimen 2#: 7 CFU/g Specimen 3#: 3 CFU/g Specimen 4#: 12 CFU/g Specimen 5#: 7 CFU/g

Bacterial Filtration Efficiency (BFE) Test

1. Purpose

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

2. Sample description was given by client

Sample description	:	Medical Face Mask for Kid
Specification	:	/
Lot Number	:	A20210305
Sample Receiving Date	:	2021-03-20

3. Test Method

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

4. Apparatus and materials

4.1 *Staphylococcus aureus* ATCC 6538 (Particle Diameter 3.0±0.3μm).
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	39	29	0	0	0	0	0	0
2	65	72	0	0	0	0	0	0
3	112	144	0	0	0	0	0	0
4	159	171	0	0	0	0	0	0
5	986	998	0	2	1	0	0	1
6	342	306	0	0	2	1	0	0
Total (*T*), CFU	1703	1720	<1	2	3	1	<1	1
Average (C), CFU	$1.7 \times 10^3 = (P_A+P_B) / 2$							
BFE ,%				99.9	99.8	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.							

Differential pressure Test

1.Purpose

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

2.Sample description was given by client

Sample description	:	Medical Face Mask for Kid
Specification	:	/
Lot Number	:	A20210305
Sample Receiving Date	:	2021-03-20

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, airflow direction from the inside of the mask to the outside of the mask) 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#	31.3	31.8	< 60	Pass
2#	31.9			
3#	31.2			
4#	32.7			
5#	32.0			

Splash Resistance Pressure Test

1.Purpose

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

2.Sample description was given by client

Sample description	:	Medical Face Mask for Kid
Specification	:	/
Lot Number	:	A20210305
Sample Receiving Date	:	2021-03-20

3.Test Method

EN 14683:2019+AC:2019(E).

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
11#	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
21#	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

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Microbial Cleanliness Test

1. Purpose

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

2. Sample description was given by client

Sample description	:	Medical Face Mask for Kid
Specification	:	/
Lot Number	:	A20210305
Sample Receiving Date	:	2021-03-20

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:

$$N_i = 3\, n_i / M$$

Microbial Cleanliness $= N_1 + N_2$

i = 1, 2.

n = Colonies of the TSA plate or the SDA Plate.

M = Weight of the mask.

Results*:

Specimen	1#	2#	3#	4#	5#
Weight of the Mask (M, g)	2.56	2.57	2.59	2.60	2.61
Colonies of the TSA Plate (n_1)	0	2	2	2	1
Colonies of the SDA Plate (n_2)	0	3	0	7	4
Aerobic Microbial Number (N_1, CFU/g)	0	3	3	3	2
Fungi Number (N_2, CFU/g)	0	4	0	9	5
Microbial Cleanliness, (CFU/g)	<1	7	3	12	7
Requirements	≤ 30				

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-

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检 测 报 告

(Test Report)

No. GPLSR32Z566645L1

样品名称 (Sample Description)	一次性医用儿童口罩 Medical Face Mask for Kid
委托单位 (Applicant)	四川艾医生医疗科技有限公司 Sichuan Ai Doctor Medical Technology Co.,Ltd.

PONY 谱尼测试
Pony Testing International Group

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检 测 结 果
(Test Results)

No. GPLSR32Z566645L1

样品名称 (Sample Description)	一次性医用儿童口罩 Medical Face Mask for Kid	样品规格 (Sample Specification)	145*95MM
委托单位 (Applicant)	四川艾医生医疗科技有限公司 Sichuan Ai Doctor Medical Technology Co.,Ltd.	商标 (Trade Mark)	——
到样日期 (Received Date)	2021-03-05	生产日期或批号 (Manufacturing Date or Lot No.)	2021.02.26 20210226
检测日期 (Test Date)	2021-03-05~2021-03-17	样品等级 (Sample Grade)	——
样品状态 (Sample Status)	正常 Normal	检测类别 (Test Type)	委托检测 Commissioning Test
检测项目 (Test Items)	见下页 See next page	检测环境 (Test Environment)	符合要求 To meet the requirements
检测方法 (Test Methods)	见下页 See next page		
所用主要仪器 (Main Instruments)	口罩细菌过滤效率检测仪 等 Mask bacteria filtration efficiency detector etc.		
备注 (Note)	1.型号：HS0602A Model：HS0602A 2.生产单位/受检单位：四川艾医生医疗科技有限公司 Manufacturer/ Tested company：Sichuan Ai Doctor Medical Technology Co.,Ltd. 3.以上样品信息由委托单位提供 The information of sample was provided by the applicant 4.该报告中检测方法由委托单位指定。 The testing methods mentioned in this report were designated by the applicant. 5.限值标准：EN 14683:2019+AC:2019(E)（IIR 型） Limit Standard：EN 14683:2019+AC:2019(E) (Type IIR)		
PONY 专用章 (Special Stamp of PONY)	编制人 (Edited by)		
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	签发日期 (Issued Date)	2021 年 03 月 17 日	

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检 测 结 果
(Test Results)

No. GPLSR32Z566645L1

序号 (S/N)	检测项目 (Test Item)	单位 (Unit)	限值 (Limit)	检测结果 (Test Result)			单项结论 (Evaluation)	检测方法 (Test Method)
1	细菌过滤效率（BFE） Bacterial filtration efficiency(BFE)	%	≥98	99.95			符合 Pass	EN 14683:2019+ AC:2019(E) 附录 B Appendix B
				>99.99				
				99.82				
				99.95				
				99.91				
2	压力差 Differential pressure	Pa/cm²	<60	A	B	C	符合 Pass	EN 14683:2019+ AC:2019(E) 附录 C Appendix C
				1-1	20.0	20.1		
				1-2	21.9			
				1-3	20.3			
				1-4	19.7			
				1-5	18.8			
				2-1	20.9	20.0		
				2-2	21.5			
				2-3	17.4			
				2-4	18.9			
				2-5	21.2			
				3-1	22.0	21.0		
				3-2	21.2			
				3-3	22.1			
				3-4	18.2			
				3-5	21.7			
				4-1	22.6	19.4		
				4-2	20.8			
				4-3	19.0			
				4-4	18.0			
				4-5	16.8			
				5-1	17.8	19.6		
				5-2	20.6			
				5-3	18.7			
				5-4	19.7			
				5-5	21.1			

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检 测 结 果
(Test Results)

No. GPLSR32Z566645L1

序号 (S/N)	检测项目 (Test Item)	单位 (Unit)	限值 (Limit)	检测结果 (Test Result)	单项结论 (Evaluation)	检测方法 (Test Method)
3	#抗溅压力 Splash resistance pressure	kPa	≥16.0	＞16.0	符合 Pass	EN 14683:2019+ AC:2019
4	微生物洁净度 Microbial cleanliness	cfu/g	≤30	23	符合 Pass	EN 14683:2019+ AC:2019(E) 附录 D Appendix D
				19		
				12		
				20		
				18		

#表示为分包项目。
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A-试样编号-测试区域编号 Test Specimen number-Test area number；B-每个测试区域的压力差 Differential pressure for each test area；C-每个试样的平均压差 The averaged differential pressure for each test specimen。

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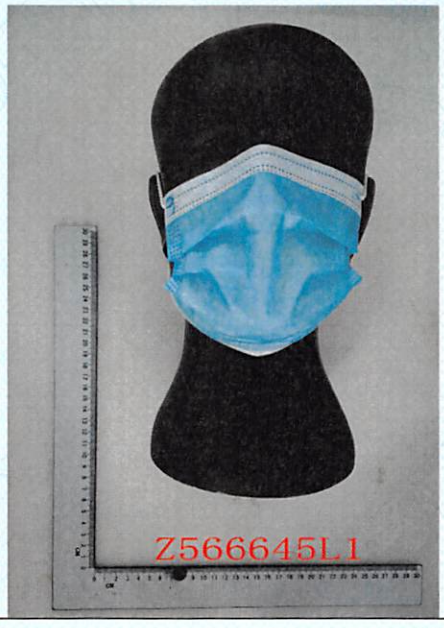

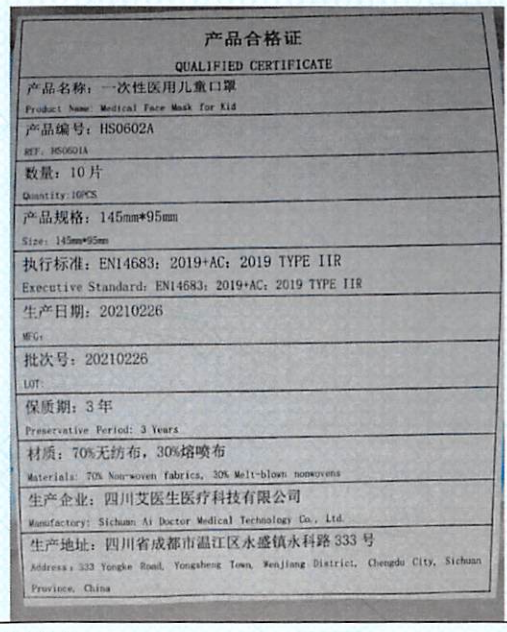

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