Nelson Labs.
A Sotera Health company

Sponsor:
Shen Yanqin
Xinxiang Tianhong Medical Device Co., Ltd
Zhaojing Town, Houjia County
Xinxiang, Henan Province, 453800
CHINA

Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article:	Company Name: Xinxiang Tianhong Medical Device Co., LTD Product Name: Disposable Medical Face Mask Type: Flat Earloop Type Lot #20200207
Study Number:	1279073-S01
Study Received Date:	20 Mar 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 18
Deviation(s):	None

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.7 - 3.0 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B.

The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test complies with EN 14683:2019, Annex C and ASTM F2100-19.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Inside
BFE Test Area:	~40 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Delta P Flow Rate:	8 Liters per minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~175 mm x ~155 mm
Positive Control Average:	2.2 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.2 µm

Liang Shuang for
Study Director James W. Luskin

27Mar2020
Study Completion Date

1279073-S01

Results:

Test Article Number	Percent BFE (%)
1	99.4
2	99.5
3	99.5
4	99.1
5	99.6

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	4.2	41.4
2	4.5	44.3
3	3.9	37.8
4	4.2	40.9
5	3.8	37.4

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} x\ 100$$

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

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CHINA

Synthetic Blood Penetration Resistance Final Report

Test Article:	Company Name: Xinxiang Tianhong Medical Device Co., LTD Product Name: Disposable Medical Face Mask Type: Flat Earloop Type Lot #20200207
Study Number:	1279074-S01
Study Received Date:	20 Mar 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0012 Rev 09
Deviation(s):	None

Summary: This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2019 and AS4381:2015) with the following exception: ISO 22609 requires testing to be performed in an environment with a temperature of 21 ± 5°C and a relative humidity of 85 ± 10%. Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Number of Test Articles Tested:	32
Number of Test Articles Passed:	29
Test Side:	Outside
Pre-Conditioning:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	22.1°C and 22% RH

Study Director: Hang Huang for James W. Luskin

26 Mar 2020
Study Completion Date

1279074-S01

Results: Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥29 of 32 test articles show passing results.

Test Pressure: 120 mmHg (16.0 kPa)

Test Article Number	Synthetic Blood Penetration
1-8, 10-20, 22-26, 28-32	None Seen
9, 21, 27	Yes

Nelson Labs
A Sotera Health company

Sponsor:
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XINXIANG TIANHONG MEDICAL DEVICE CO., LTD
ZHAOJING TOWN, HOUJIA COUNTY
XINXIANG, HENAN PROVINCE, 453800
CHINA

Microbial Cleanliness (Bioburden) of Medical Masks Final Report

Test Article:	Company Name: Xinxiang Tianhong Medical Device Co., LTD Product Name: Disposable Medical Face Mask Type:Flat Earloop Type Lot #20200207
Study Number:	1279072-S01
Study Received Date:	20 Mar 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0036 Rev 15 Customer Specification Sheet (CSS) Number: 202001635 Rev 01
Deviation(s):	None

Summary: The testing was conducted in accordance with EN 14683:2019, with the exception of approximate volumes of eluent used when performing the extraction procedure and a temperature range of 30-35°C used for aerobic incubation.

When bioburden results are calculated using a software program, manual calculations may differ slightly due to rounding. The counts determined on products are colony forming units and may not always reflect individual microorganisms. The sponsor performs any statistical analysis and determines the acceptable limits. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Results:

Unit Number	Weight (g)	Aerobic	Fungal	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	3.6	<3	<3	<6.0	<1.7
2	3.4	<3	<3	<5.9	<1.7
3	3.6	<3	<3	<6.3	<1.8
4	3.4	<3	<3	<6.2	<1.9
5	3.6	<3	<3	<6.0	<1.7
Recovery Efficiency	UTD[a]				

< = No Organisms Detected
UTD = Unable to determine
Note: The results are reported as colony forming units (CFU) per mask.
[a] UTD due to zero count on the first rinse. An alternate method or inoculated product recovery efficiency is recommended.

Robert Putnam electronically approved — 02 Apr 2020 15:00 (+00:00)
Study Director Robert Putnam — Study Completion Date and Time

Test Method Acceptance Criteria: If applicable, anaerobic controls are acceptable for the bioburden test results.

Procedure:

Positive Controls/Monitors:	*Bacillus atrophaeus*
Extract Fluid:	Peptone Tween®
Extract Fluid Volume:	~300 mL
Extract Method:	Orbital Shaking for 15 minutes at 250 rpm
Plating Method:	Membrane Filtration
Agar Medium:	Potato Dextrose Agar Tryptic Soy Agar
Recovery Efficiency:	Exhaustive Rinse Method
Aerobic Bacteria:	Plates were incubated 3 days at 30-35°C, then enumerated.
Fungal:	Plates were incubated 7 days at 20-25°C, then enumerated.

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

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minvws.nl

Ons kenmerk:
CIBG-20200686

Bijlagen
-

Uw aanvraag
17 maart 2020

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

Datum: 20 maart 2020
Betreft: aanmelding medisch hulpmiddel klasse I

Geachte heer Luo,

Graag bevestig ik hierbij de ontvangst op 17 maart 2020 van de mededeling ex artikel 5 van het Besluit medische hulpmiddelen (BMH) dat bedrijf Xinxiang Tianhong Medical Device Co.,LTD met Europees gemachtigde SUNGO Europe B.V. onderstaand medisch hulpmiddel, ingedeeld in risicoklasse I, aflevert. Het product is onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie betreffende dit product het bijbehorende kenmerk te vermelden.

Disposable Medical Face Mask
(geen merknaam) (NL-CA002-2020-49703)

Toekomstige wijzigingen in bovengenoemde gegevens – waaronder een eventuele wijziging van de indeling in risicoklasse in verband met wijzigingen van Europese regelgeving inzake de classificatie van medische hulpmiddelen, en aan voortschrijdend wetenschappelijk inzicht (zie art.9, lid 3 van Europese Richtlijn 93/42/EEG) – dient u te zijner tijd mede te delen.

Volledigheidshalve wijs ik u erop dat het - ongeacht uw mededeling – verboden is een medisch hulpmiddel ter aflevering voorhanden te hebben, dan wel af te leveren indien niet aan de voor dat medisch hulpmiddel geldende regels gesteld bij of krachtens de Wet op de Medische Hulpmiddelen (WMH) wordt voldaan. Met name wijzen wij u op de Nederlandse-taaleis, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Market Surveillance- en vigilantiesysteem.

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.

Let op: de notificatie van uw MDD klasse I product vervalt per 26 mei 2020.
Valt uw MDD klasse I (laag risico) product onder de nieuwe VERORDENING (EU) 2017/745 (MDR) onder een hogere risicoklasse? Dan mag uw product tot en met uiterlijk 25 mei 2024 op de markt blijven als MDD klasse I product.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec

Dr. M.J. van de Velde

Dhr. M.J. van de Velde

ZERTIFIKAT ◆ 認證證書 ◆ CERTIFICATE

CERTIFICATE OF NOTIFICATION

This is to certify that, according to the council regulation 2017/745/EU, SUNGO performed all notification duties and responsibilities as the European authorized representative of:

Applicant:	Xinxiang Tianhong Medical Device Co.,LTD
Address:	Zhaojing Town,Huojia County,Xinxiang City,Henan Province,China

The Manufacturer has provided SUNGO with all the appropriate declarations according to the 2017/745/EU Regulation requirements including the EC Declaration of Conformity confirming that his medical device, as stipulated here below, is fulfilling the applicable requirements of the European Council Regulation 2017/745/EU.

Product(s):	Disposable Medical Face Mask
Type(s):	A: earloop face mask B: face mask with ties
Product Classification:	Class I

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU regulation(s) have and continue to be met.

The notification of aforementioned device has been completed by the European Representative in Netherlands. The Netherlands Competent Authority is notified of the manufacturer's medical devices and has allocated registration. NOTIS number is CIBG-20200686.

SUNGO
Executive Director
Sungo global service
CERTIFIED

Issued: Mar. 30 2020

Cert. No.: EU231518

Expiration Date: Mar. 29 2025

CE

This is not a CE mark and is only provided as a template for informational purpose.

ZERTIFIKAT ◆ 認證證書 ◆ CERTIFICATE