Inhaltsverzeichnis Zertifikate / Prüfberichte
Ordner EMIX Trading AG, *Stand 01.02.2022*

4.1	**Angtai KN95**
4.2	**Chemipharma**
4.3	**Gaidien 3 Ply**
4.4	**Guanhua KN95**
4.5	**Naisian KN95**
4.6	**Pinyue KN95**
4.7	**SWORD 3 PLY**
4.8	**Teyin FFP2**
4.9	**YI Cheng KN95**
4.10	**Yeufon 3 Ply**
4.11	**Yeufon KN95**

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 18 01 65303 013

Manufacturer:

Sword Xiantao Disposable Protective Products Factory
Liukou Industrial Zone
433000 Xiantao City, Hubei Province
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

Non Woven Cap, Non Woven Face Mask, Surgical Gown, Coverall, Non Woven Shoe Cover, Surgical Drape, Isolation Gown, Oversleeves, Disposable Examination Gloves, Wooden Tongue Depressor, Wooden Vaginal Spatula, Cotton Tip, Under Pad, Beard Cover, Surgical Kit, Protection Coat, Apron, Neck Paper, Dental Bib, Dental Kit, First-aid Kit (Case) , Patient Kit

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH18298EXT01

Valid from: 2018-03-20
Valid until: 2023-03-19

Date, 2018-02-23

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 18 01 65303 013

Facility(ies):

Sword Xiantao Disposable Protective Products Factory
Liukou Industrial Zone, 433000 Xiantao City, Hubei Province, PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

EC-Declaration of Conformity

Manufacturer:	Sword Xiantao Disposable Protective Products Factory Liukou Industrial Zone, 433000 Xiantao City, Hubei Province, PEOPLE'S REPUBLIC OF CHINA
European Authorized Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg,Germany
Device Name and Variants:	Non Woven Face Mask
UMDNS code:	12458
Classification:	I, Rule 1
Conformity Assessment Route:	Directive 93/42/EEC Annex VII

We hereby to certify that under our sole responsibility the above mentioned product conforms to the procisions of the following EC Council Directives and Standards. All Supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC concerning medical devices (MDD 93/42/EEC), amended by 2017/47/EC.

Start of CE Marking:	2019-07-15
Place, Date of Issue:	Xiantao, 2020-03-13
Signature/Date:	
Management Representative:	Mr. Li Hanhua

Nelson Labs.
A Sotera Health company

Sponsor:
Li Jun
Sword Xiantao Disposable Protective Products Factory
Liukou Industrial Zone 433000 Xiantao City
Hubei Province, Xiantao, 433000
PEOPLE'S REPUBLIC OF CHINA

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

Test Article:	Product Name: Non Woven Face Mask Lot #2020030103
Study Number:	1285390-S01
Study Received Date:	07 Apr 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 4.1×10^3 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; with the exception of the higher challenge level, which may represent a more severe test.

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.

The positive control average was out of specification per STP0004 Rev 18 section 6.1 which states, "The BFE positive control average shall be maintained at $1.7\text{-}3.0 \times 10^3$ CFU." Testing with a more severe challenge to the test articles represents a worse case. The sponsor accepted the use of the higher challenge; therefore, the results are considered valid at the testing conditions that occurred.

Test Side:	Inside
BFE Test Area:	~40 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Delta P Flow Rate:	8 L/min
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~170 mm x ~167 mm
Positive Control Average:	4.1×10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.7 µm

Yang Yuang for
Study Director James W. Luskin

28 Apr 2020
Study Completion Date

1285390-S01

Results:

Test Article Number	Percent BFE (%)
1	>99.9
2	>99.9
3	>99.9
4	99.9
5	>99.9

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	5.6	54.6
2	5.4	52.6
3	5.3	51.8
4	5.2	50.8
5	5.7	55.6

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

Nelson Labs.
A Sotera Health company

Sponsor:
Li Jun
Sword Xiantao Disposable Protective Products
Liukou Industrial Zone
Xiantao City, Hubei Province 433000
PEOPLE'S REPUBLIC OF CHINA

Synthetic Blood Penetration Resistance Final Report

Test Article:	Product Name: Non Woven Face Mask Lot #2020030103
Study Number:	1285388-S01
Study Received Date:	07 Apr 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:	30
Test Side:	Outside
Pre-Conditioning:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	20.3°C and 22% RH

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
1-9, 11-19, 21-32	None Seen
10, 20	Yes

Study Director James W. Luskin

20 Apr 2020
Study Completion Date

1285388-S01

Nelson Labs.
A Sotera Health company

Sponsor:
Li Jun
Sword Xiantao Disposable Protective Prod
Liukou Industrial Zone 433000 Xiantao City
Hubei Province
PEOPLE'S REPUBLIC OF CHINA
Xiantao, 433000
CHINA

Microbial Cleanliness (Bioburden) of Medical Masks Final Report

Test Article:	Product Name: Non Woven Face Mask Lot No.:2020030103
Study Number:	1285389-S01
Study Received Date:	07 Apr 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: 202001633 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	3.8	<3	<3	<5.9	<1.5
2	3.8	<3	<3	<6.0	<1.6
3	3.9	<3	<3	<5.7	<1.5
4	3.8	<3	<3	<6.1	<1.6
5	4.0	<3	<3	<5.7	<1.4
Recovery Efficiency	UTD[a]				

< = No Organisms Detected
UTD = Unable to Determine
Note: The results are reported as colony forming units per test article.
[a] UTD due to zero count on the first rinse. An alternative method or inoculated product recovery efficiency is recommended.

Carl Danielson electronically approved for
Study Director — Robert Putnam

21 Apr 2020 16:11 (+00:00)
Study Completion Date and Time

Method Suitability:

Organism	Percentage
Bacillus atrophaeus	116%

Test Method Acceptance Criteria: If applicable, anaerobic controls are acceptable for the bioburden test results. The number of masks to be tested shall be a minimum of 5 or more to meet an acceptable quality level of 4%. The bioburden of the medical mask shall be < 30 CFU/g tested.

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.

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America

CERTIFICATE

No. QS5 065303 0016 Rev. 00

Certificate Holder:

Sword Xiantao Disposable Protective Products Factory
Liukou Industrial Zone
433000 Xiantao City, Hubei Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate:

Production and Distribution of Disposable / Re-Usable (Antistatic) Cap, Face Mask, Gloves, Cover, Neck Paper, Gowns and Accessories, Apron, Coverall, Uniform, Pajama, Bags, Slippers, Sheets, Drape, Under Pad, Bib, Cotton Tip

Standard(s): **ISO 9001:2015**

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: **TAM / SH1929813**

Effective Date: **2020-09-18**

Expiry Date: **2023-02-26**

Page 1 of 1
Date of Issue: 2020-10-12

Tina Israel
Manager, US Certification Body,
Medical and Health Services

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q6 065303 0015 Rev. 00

Holder of Certificate: **Sword Xiantao Disposable Protective Products Factory**
Liukou Industrial Zone
433000 Xiantao City, Hubei Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Sword Xiantao Disposable Protective Products Factory
Liukou Industrial Zone, 433000 Xiantao City, Hubei Province,
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Production and Distribution of Non Woven Cap, Non Woven Face Mask, Surgical Gown, Coverall, Non Woven Shoe Cover, Surgical Drape, Isolation Gown, Oversleeves, Disposable Examination Gloves, Wooden Tongue Depressor, Cotton Tip, Wooden Vaginal Spatula, Under Pad, Single Use Dental Kit, Single Use Surgical Procedure Packs, Dental Bib, Medical Apron, Beard Cover, Protection Coat, Neck Paper, First-aid Kit(Case), Patient Kit**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.:	TAM / SH1929813
Valid from:	2020-03-17
Valid until:	2023-02-28

Date, 2020-03-17

Christoph Dicks
Head of Certification/Notified Body

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