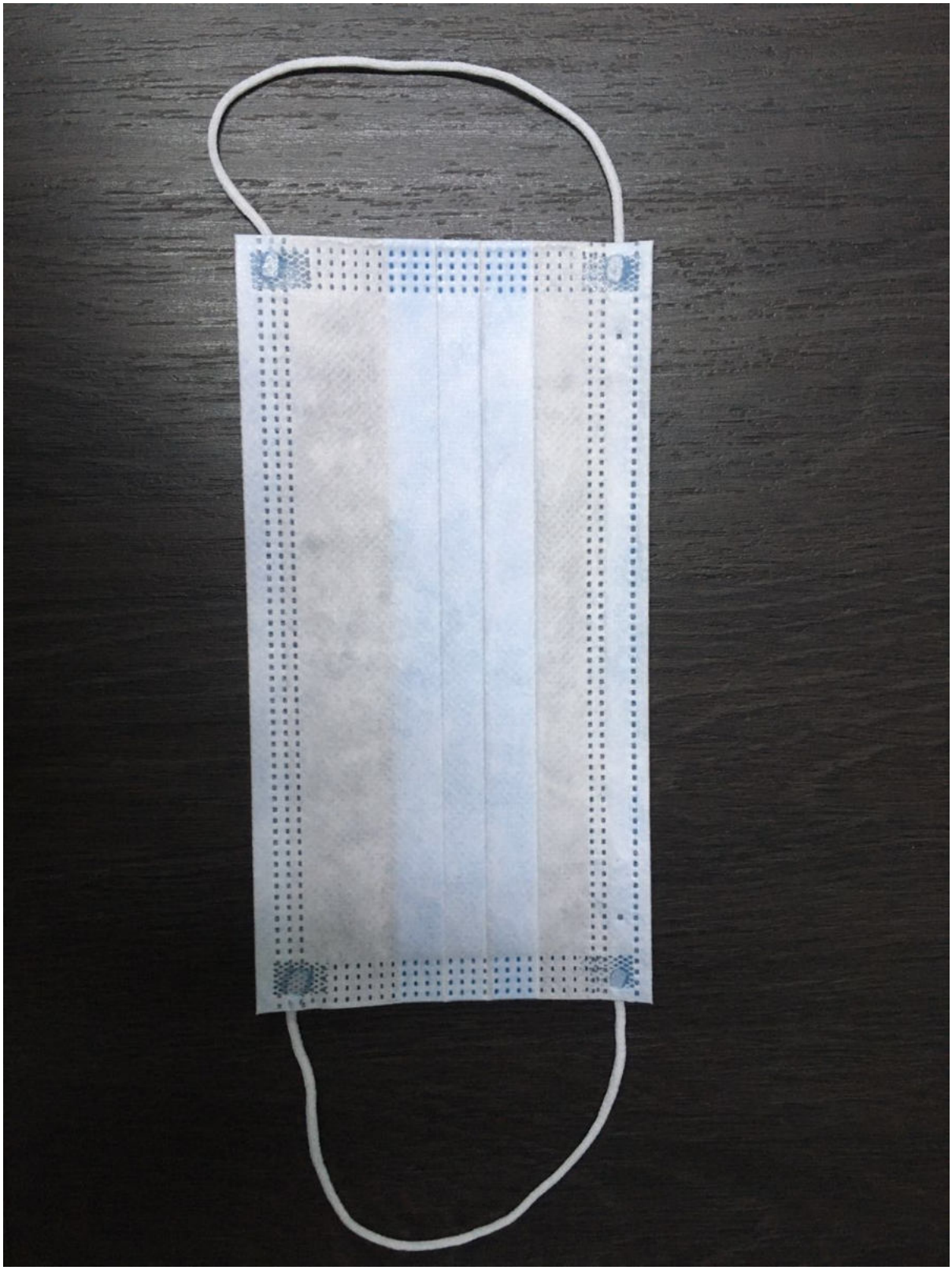

Disposable
Medical Face Mask
Type IIR
WITH EARLOOP
50 PCS/BOX




Type IIR
WITH EARLOOP
50 PCS/BOX
Disposable
Medical Face Mask
Type IIR
• 3-Ply for better protection
• 100% fiberglass free
• Strong nose guard for extra comfort
• Latex free elastic
REF CN102
50 PCS
WITH EARLOOP


50 PCS/BOX
Disposable
Medical Face Mask


Instruction
Before putting on mask, clean hands with alcohol-based hand sanitizers, or soap and water
Cover your mouth and nose with mask and make sure to have minimum gaps between your face and mask
Avoid touching the mask while using it
Replace mask with new one when damp
Dispose the mask after use
Manufacturer
Products Fty., Ltd
District, Wuhan City, China
MADE IN CHINA


Disposable
Medical Face Mask
Type IIR
Size: 17.5X9.5cm
REF CN102
2000
40X50 pieces

Crow[redacted]ne Products Fty., Ltd.

Also trading as Crov[redacted] Co., Ltd.

Directive 93/42/EEC

on medical devices, Annex V
Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions

Issue 1

Detailed scope

Sterile Surgical Kits (Surgical Gown used to protect the patient from contamination and also to protect the hospital staff, Surgical Drape, Face Mask, Cap used to protect the patient from contamination and also to protect the hospital staff)

Additional facilities

Changhang Building Rm.1805 18/F, No. 69, Yanjiang Avenue, Wuhan City, Hubei Province, 430021, P.R.China

EC Certificate Production Quality Assurance System: Certificate CN19/41065

The management system of

Crow[redacted]iene Products Fty., Ltd.

Also trading as Crow[redacted] Co., Ltd.

Cheng[redacted]strict,
Wuhan City, Hubei Province, 43[redacted], China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V
Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 16 December 2019 until 19 July 2022
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 24 November 2015
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered CN/SZH/ 8618

This is a multi-site certification.
Additional site details are listed on subsequent pages.

Authorised by

Pieter Weterings
Certification Manager

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

Certificate CN14/21395

The management system of

Crow[redacted]iene Products Fty., Ltd.

Also trading as Crow[redacted] Co., Ltd.

Cheng[redacted]u District,
Wuhan City, Hubei Province, [redacted]R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 09 April 2018 until 21 October 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 25 April 2020
Issue 4. Certified since 22 October 2014

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118 M2

Crow[redacted]iene Products Fty., Ltd.

Also trading as Crow[redacted]b., Ltd.

ISO 13485:2016
EN ISO 13485:2016

Issue 4

Detailed scope

Manufacture of sterile and non sterile nonwoven medical devices: Surgical Gowns, Surgical drapes, Face masks, Caps, Overalls, Shoe covers, Sleeves, Head covers, Table Cover, Isolation gown, Air-laid paper, Surgical kits (surgical gown, surgical drape, face mask, cap)

Additional facilities

Changhang Building Rm.1805 18/F, No. 69, Yanjiang Avenue, Wuhan City, Hubei Province, 430021, P.R. China

UKAS MANAGEMENT SYSTEMS
0005

NELSON LABORATORIES

Sponsor:
[redacted]
Crow[redacted]ene Products Fty.Ltd.
Cheng[redacted]e.
Xinzhou District
Wuhan, Hubei, 431400
CHINA

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

Test Article:	CNMB001
Purchase Order:	Q-52955-V9F7P7
Study Number:	956725-S01
Study Received Date:	04 Apr 2017
Test Procedure(s):	Standard Test Protocol (STP) Number: 801-STP0004 Rev 14

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 - 2.7 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 F2101-14 and EN 14683:2014, 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 was designed to comply with MIL-M-36954C, Section 4.4.1.2 and complies with EN 14683:2014, Annex C.

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:	Either
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
Positive Control Average:	1.8 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.1 µm

ANAB ACCREDITED TESTING LABORATORY

Study Director: Trang Truong — Trang T. Truong, B.S.

14Apr2017
Study Completion Date

956725-S01

Results:

Test Article Number	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	99.0	1.7	17.1
2	99.4	1.5	15.0
3	99.2	1.6	15.6
4	99.0	1.6	15.8
5	99.1	1.6	16.1

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 LABORATORIES

Sponsor:
[redacted]
[redacted]ts Co. Ltd.,
Chengl[redacted]u District
Wuhan, Hubei Province, 431400
CHINA

Latex Particle Challenge Final Report

Test Article:	ZSTS001
Purchase Order:	ZSTS001
Study Number:	999136-S01
Study Received Date:	27 Oct 2017
Testing Facility:	Nelson Laboratories, LLC, a Business Unit of Sterigenics International 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0005 Rev 05
Deviation(s):	None

Summary: This procedure was performed to evaluate the non-viable particle filtration efficiency (PFE) of the test article. Monodispersed polystyrene latex spheres (PSL) were nebulized, dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

Three one-minute counts were performed, with the test article in the system, and the results averaged. Three one-minute control counts were performed, without a test article in the system, before and after each test article and the counts were averaged. Control counts were performed to determine the average number of particles delivered to the test article. The filtration efficiency was calculated using the average number of particles penetrating the test article compared to the average of the control values.

The procedure employed the basic particle filtration method described in ASTM F2299, with some exceptions; notably the procedure incorporated a non-neutralized challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks. 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
Area Tested:	91.5 cm^2
Particle Size:	0.1 µm
Laboratory Conditions:	21°C, 28% relative humidity (RH) at 0734; 21°C, 29% RH at 0945
Average Filtration Efficiency:	99.80%
Standard Deviation:	0.031

ilac-MRA ANAB ACCREDITED TESTING LABORATORY

Study Director Brandon L. Williams — 08 Nov 2017 Study Completion Date

999136-S01

Results:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	29	13,984	99.79
2	25	13,348	99.81
3	33	13,160	99.75
4	21	12,922	99.83
5	28	13,459	99.79

NELSON LABORATORIES

Sponsor:
[redacted]
Wuh[redacted] Co. Ltd.,
Cheng[redacted]ou District
Wuhan, Hubei Province, 431400
CHINA

Synthetic Blood Penetration Resistance Final Report

Test Article:	ZSTS001
Purchase Order:	ZSTS001
Study Number:	998110-S01
Study Received Date:	23 Oct 2017
Testing Facility:	Nelson Laboratories, LLC, a Business Unit of Sterigenics International 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0012 Rev 08
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 14683:2014 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:	21.0°C and 24% 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
1-17, 20-32	None Seen
18, 19	Yes

Study Director Brandon L. Williams — Study Completion Date 03 Nov 2017

998110-S01