

CERTIFICATE

No. SCI001MD

certifies that:

MED-CON (THAILAND) CO., LTD.

47 Moo 5, Bangkrauy-Sainoi Rd., Sainoi, Nonthaburi 11150 Thailand

operates a management system that has been assessed as conforming to:

ISO 13485:2016

for the scope of activities:

Design and Manufacture of Disposable Facemasks, Disposable Caps, Sterile and Non-Sterile Gowns for Medical Purposes, Surgical Gowns, Isolation Gowns, Shoe Covers, Boot Covers, Spandex Elastic, Headrest Covers, Pillow Case, Disposable Pillow Sheet, Sterile and Non-Sterile Medical Gauzes, Disposable Wraps, Disposable Bed Sheet, Disposable Panties, Sterilization Pouch Roll and Surgical Drape

Issue date: **26/06/2020**

Valid until: **25/06/2023** (Subject to adherence to the agreed ongoing programme, successful endorsement of certification following each audit and compliance with the terms and conditions of certification.)

Original date of certification: **06/08/2014**

Sita Prawarnpit , Managing Director



CERTIFICATE

No. SCU002982Q

certifies that:

Med-Con (Thailand) Co., Ltd

47 Moo 5, Bangkruay-Sainoi Rd., Sainoi, Nonthaburi, 11150, Thailand

operates a management system that has been assessed as conforming to:

ISO 9001 : 2015

for the scope of activities:

Design and Manufacture of Disposable Facemasks, Disposable Caps, Sterile and Non-Sterile Gowns for Medical Purposes, Surgical Gowns, Isolation Gowns, Shoe Covers, Boot Covers, Spandex Elastic, Headrest Covers, Pillow Case, Disposable Pillow Sheet, Sterile and Non-Sterile Medical Gauzes, Disposable Wraps, Disposable Bed sheet, Disposable Panties, Sterilization Pouch Roll and Surgical Drape

Issue date: **1st July 2019**

Valid until: **7th January 2021** (Subject to adherence to the agreed ongoing programme, successful endorsement of certification following each audit and compliance with the terms and conditions of certification.)

Original date of certification: **1st February 2005**

Matthew Westby Operations Director UK





CERTIFICATE

No. SCUUK002983E

certifies that:

Med- Con (Thailand) Co., Ltd.

47 Moo 5, Bangkruay-Sainoi Rd., Sainoi, Nonthaburi 11150, Thailand

operates a management system that has been assessed as conforming to:

ISO 14001 : 2015

for the scope of activities:

Design and Manufacture of Disposable Facemasks, Disposable Caps, Sterile and Non-Sterile Gowns for Medical Purposes, Surgical Gowns, Isolation Gowns, Shoe Covers, Boot Covers, Spandex Elastic, Headrest Covers, Pillow Case, Disposable Pillow Sheet, Sterile and Non-Sterile Medical Gauzes, Disposable Wraps, Disposable Bed sheet, Disposable Panties, Sterilization Pouch Roll and Surgical Drape

Issue date: **1st July 2019**

Valid until: **7th January 2021** (Subject to adherence to the agreed ongoing programme, successful endorsement of certification following each audit and compliance with the terms and conditions of certification.)

Original date of certification: **14th January 2005**

Matthew Westby Operations Director UK



SOCOTEC Certification UK Ltd - 6 Gordano Court -
Serbert Close- Portishead - Bristol BS20 7FS
UNITED KINGDOM
www.socotec-certification-international.com

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

Test Article: MCBJJ-1095-BFE
Study Number: 1196118-S01
Study Received Date: 25 Jun 2019
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 16
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 $1.7 - 2.7 \times 10^3$ colony forming units (CFU) with a mean particle size (MPS) of $3.0 \pm 0.3 \mu\text{m}$. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-14, Annex B, and AS4381:2015.

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 AS4381:2015.

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: $\sim 40 \text{ cm}^2$
BFE Flow Rate: 28.3 Liters per minute (L/min)
Delta P Flow Rate: 8 L/min
Conditioning Parameters: $85 \pm 5\%$ relative humidity (RH) and $21 \pm 5^\circ\text{C}$ for a minimum of 4 hours
Test Article Dimensions: $\sim 177 \text{ mm} \times \sim 164 \text{ mm}$
Positive Control Average: 1.8×10^3 CFU
Negative Monitor Count: < 1 CFU
MPS: $2.9 \mu\text{m}$

(THAILAND)
CO., LTD.




Study Director

For
Janelle R. Bentz, M.S.

15 Jul 2019
Study Completion Date



1196118-S01

Results:

Test Article Number	Percent BFE (%)	Delta P (mm H ₂ O/cm ²)	Delta P (Pa/cm ²)
1	>99.9	2.2	21.7
2	99.5	2.5	24.2
3	99.6	2.5	24.5
4	99.4	2.3	22.9
5	99.8	2.2	21.1

The filtration efficiency percentages were calculated using the following equation:

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

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request



Latex Particle Challenge Final Report

Test Article: ID: Medimask, 3 Ply Facemask
Lot: 2103
Study Number: 1410634-S01
Study Received Date: 21 Apr 2021
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: STP0005 Rev 08
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 (atomized), dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

A one-minute count was performed, with the test article in the system. A one-minute control count was performed, without a test article in the system, before and after each test article. Control counts were performed to determine the average number of particles delivered to the test article. The filtration efficiency was calculated using the number of particles penetrating the test article compared to the average of the control values. During testing and controls, the air flow rate is maintained at 1 cubic foot per minute (CFM) $\pm$ 5%.

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 cm²
Particle Size: 0.1 μ m
Laboratory Conditions: 22.3°C, 21% relative humidity (RH) at 2203; 22.2°C, 21% RH at 2253
Average Filtration Efficiency: 99.91%
Standard Deviation: 0.040



Cameron Brierley electronically approved
Study Director

Cameron Brierley

29 Apr 2021 21:41 (+00:00)
Study Completion Date and Time

Results:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	9	12,683	99.929
2	6	12,666	99.953
3	10	12,936	99.923
4	18	12,877	99.86
5	17	13,093	99.87



Viral Filtration Efficiency (VFE) Final Report

Test Article: ID: Medimask, 3 Ply Facemask
Lot: 2103
Study Number: 1414095-S01
Study Received Date: 03 May 2021
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: STP0007 Rev 16
Deviation(s): None

Summary: The VFE test is performed to determine the filtration efficiency of test articles by comparing the viral control counts upstream of the test article to the counts downstream. A suspension of bacteriophage ΦX174 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 $1.1 - 3.3 \times 10^3$ plaque forming units (PFU) with a mean particle size (MPS) of $3.0 \mu\text{m} \pm 0.3 \mu\text{m}$. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. The VFE test procedure was adapted from ASTM F2101.

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
Test Area: $\sim 40 \text{ cm}^2$
VFE Flow Rate: 28.3 Liters per minute (L/min)
Conditioning Parameters: $85 \pm 5\%$ relative humidity (RH) and $21 \pm 5^\circ\text{C}$ for a minimum of 4 hours
Positive Control Average: 2.8×10^3 PFU
Negative Monitor Count: <1 PFU
MPS: $2.9 \mu\text{m}$

(THAILAND)
CO., LTD.



Mikell Goldsberry electronically approved
Study Director

Mikell Goldsberry

14 May 2021 02:37 (+00:00)
Study Completion Date and Time

Results:

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

The filtration efficiency percentages were calculated using the following equation:

$$\% VFE = \frac{C - T}{C} \times 100$$

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request

