

TEST REPORT

Applicant: SUNLIGHT ECO-TECH LIMITED
UNIT D 2/F SPEEDY IND BLDG
114 HOW MING ST
KWUN TONG
KLN HK

Date: May 20, 2020

Attn: MARTIN Z.LI

Sample Description As Declared :

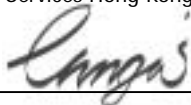
No. Of Sample : Several
Buyer's Name : -
Agent's Name : -
Manufacturer's Name : Sunlight Eco-Tech Limited
Sample Description : Mask
Colour : Blue
Style No. : -
Order No. / PO No. : -
Product End Uses : -
Fibre Content : -
Fabric/GMT Weight : -
Ref. : -

Date Received/Date Test Started : Apr 08, 2020

Applicant's Provided Care Instruction/Label :

-

For and on behalf of
Intertek Testing Services Hong Kong Limited

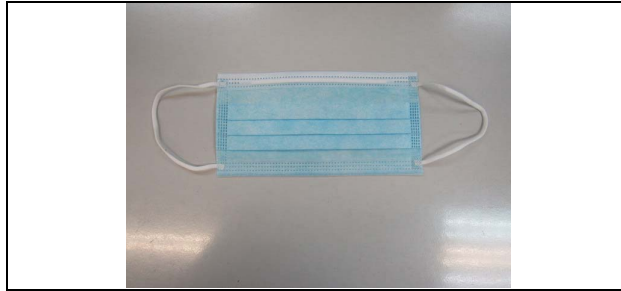


Teddy Y. N. Chung
Director



TEST REPORT

Original Sample Photo:

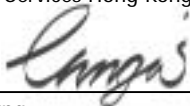


For any queries on this report, you are welcome to contact our customer service representatives:

EM3

Angie Yu (852) 98639123 or email to angie.yu@intertek.com

For and on behalf of
Intertek Testing Services Hong Kong Limited



Teddy Y. N. Chung
Director



TEST REPORT

Tests Conducted (As Requested By The Applicant)

1 Synthetic Blood Penetration Resistance GLP Report:

Summary: The test 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 AS 4381:2015) 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 $85 \pm 10\%$. 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.

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 $85 \pm 5\%$ relative humidity (RH)

Test Conditions: 20.7 °C and 22% RH

Result: 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
1-7, 9, 11-13, 15-32	None Seen
8, 10, 14	Yes

Test Method Acceptance Criteria: The output of synthetic blood passing through the targeting hole before and after every set of test articles must be $\leq 5\%$ (± 0.10 g) in difference from the theoretical output of 2 mL.

Procedure: A clean cannula was fixed onto the front of the valve and reservoir was filled with synthetic blood. The reservoir pressure and timer were set to allow a differential weight of 95 – 102%. This was achieved by setting the valve timer to 0.5 seconds and 1.5 seconds, collecting and weighing the amount of fluid before and after the targeting hole, and then calculating the weight differences for the deliveries. After the reservoir pressure and timer duration has been adjusted, the 2 mL spray was verified by dispensing three spurts in a row through the targeting hole into a graduated cylinder and weighing. After every 16 test articles, synthetic blood was delivered into a graduated cylinder and weighed to ensure the test apparatus was still delivering 2 mL of synthetic blood.



TEST REPORT

Tests Conducted (As Requested By The Applicant)

Synthetic Blood Penetration Resistance GLP Report (Cont'd)

Each test article was tested within one minute of removal from the conditioning chamber. The facemask was mounted on the test articles holding fixture and positioned 305 mm (12 in) from the cannula. The mask was then subjected to the 2 mL volume spray, which moved from the cannula in a horizontal path perpendicular to the facemask. This procedure used a targeting hole that blocked the initial, high-pressure portion of the synthetic blood stream and allowed only the fluid travelling at the target velocity to hit the center of the mask. Each test articles was observed for penetration within 10 seconds of dispensing the synthetic blood against the target area.

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211 and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	30 Apr 2020
Phase Inspected by Quality Assurance: Penetration Test	04 May 2020
Audit Results Reported to Study Director	08 May 2020
Audit Results Reports to Management	11 May 2020

Data Disposition: The study plan, raw data and final report from this study are archived at competent subcontractor laboratory.

Remark: The test was conducted by competent subcontractor laboratory.

End of Report

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