TEST REPORT

Hardline Laboratory

Report No. : HL90642B/2020
Page : 1 of 5
Date : DEC. 31, 2020

Durio PPE Sdn. Bhd.
No. 16, Jalan Temenggong, 81100 Johor Bahru, Johor, Malaysia

The following merchandise was submitted and identified by the applicant as:

Product Description: Durio Surgical Mask
Country of Origin: Malaysia

We have tested the submitted sample(s) as requested and the following results were obtained:

Test Requested:
1. ISO 11737-1:2018
2. EN 14683:2019 Annex B
3. EN 14683:2019 Annex C
4. 16 CFR Part 1610

Test Method & Result: ---See following sheet(s)---

Date of Receipt: SEP. 29, 2020

Testing Period: SEP. 29, 2020 ~ NOV. 30, 2020

Note: 1. The ISO 11737-1:2018 testing was performed by Europe America Biotechnology Co., Ltd.
2. The EN 14683:2019 Annex B, EN 14683:2019 Annex C and 16 CFR Part 1610 tests were performed by O.S.H. CO., LTD. Respirator Test Center.

Signed for and on behalf of SGS Taiwan Ltd.

Sturm Su
Asst. Manager

Test Method & Result:

1. ISO 11737-1:2018:

Test Article:

The following information of the test article was supplied by the sponsor.

Name: Durio Surgical Mask
Lot No.: N/A
Model No.: N/A
Article No.: T-1091007-02

Purpose:

The purpose of the study was to evaluate the total number of viable microorganisms on a medical device before sterilization.

Materials:

Test Article: Durio Surgical Mask

Other Materials:

Tryptic Soy Agar (TSA)
Peptone Water
Sample bag

References:

The test was conducted based upon the following reference:

ISO 11737-1:2018(E) Sterilization of health care products-Microbiological methods - Part 1: Determination of population of microorganisms on products.

Method:

Test Procedure: (SOP: EA-WI-013)

Test article's packing was aseptically opened in the laminar flow hood. Test article was cut into small pieces and transferred to sample bag containing 150 ml peptone water. Test article was extracted by ultrasonic bath and then tested for aerobic, anaerobic, and fungal counts using the membrane filtration method. Three 0.45 μm membranes with 50 ml filtered extract were placed individually onto Tryptic Soy Agar (TSA) plates for aerobic, fungal and anaerobic counts. A negative control with only peptone water was performed to ensure that the test results were reliable. The aerobic and anaerobic were incubated at 30~35 °C for 7 days, while fungal were incubated at 20~ 25 °C for 7 days.

Results:

Sample No.	Aerobic (CFU/Sample)	Fungal (CFU/Sample)	Anaerobic (CFU/Sample)
#1	12	8	< 3
#2	12	14	2
#3	2	2	2
#4	12	12	< 3
#5	10	10	< 3
#6	4	2	2
#7	4	< 3	< 3
#8	12	4	< 3
#9	4	6	2
#10	4	< 3	< 3
Average (CFU/Sample)	7.6	5.8	0.8
*Average (CFU/g)	2.1 (CFU/g)	1.6 (CFU/g)	0.2 (CFU/g)
Negative control	0	0	0

Remarks: 1. SIP= 0.5, SIP (Sample Item Portion) is the portion of sample under analysis.
1.0 represents a full piece. Above data has been calculated by SIP.
2. < 3= No organisms detected.
3. CFU =Colony Forming Units.
4. *: Average weight for single mask is 3.6 g; average (CFU/g) is obtained from average (CFU/Sample) ÷ 3.6 g.
5. Sample Model: EABML(E)1091023-329

2. EN 14683:2019 Annex B:

Test Methods	Test Item		Test Results
1. Testing Sample Number: 5 2. Sample Dimensions：~9.5 cm x ~17.2 cm 3. Test surface : Outside 4. Test Area: 49 cm^2 5. Flow rate during testing: 28.3 Liter/min 6. Counts of positive control: 2235 CFU 7. Counts of negative control: 0 CFU 8. Average size: 3.0 μm 9. Sample Model: BFE-1091008001	Bacterial filtration efficiency (BFE) (%)	01	>99.9
		02	>99.9
		03	>99.9
		04	>99.9
		05	>99.9

3. EN 14683:2019 Annex C:

Test Methods	Test Item		Test Results (mm H_2O/cm^2)	Test Results (Pa/cm^2)
1. Testing Sample Number: 5 2. Test Flow Rate：8.00 Liter/min 3. Pre-Conditioning: Minimum of 4 hours at (21±5) ℃ and (85±5) % relative humidity. 4. Sample Model: AEP-1091008001	Differential pressure	01	3.34	32.73
		02	3.34	32.73
		03	3.45	33.81
		04	3.44	33.71
		05	3.54	34.69
		Avg.	3.42	33.54

4. 16 CFR Part 1610

Test Methods	Test Item		Test Results
1. 16 CFR Part 1610 Step 1：Testing in the original state. Step 2：Refurbishing and testing after refurbishing, was not performed. 2. This 16 CFR Part 1610 standard specifies that 10 replicates are to be tested it, during preliminary testing, only 1 test article exhibits flame spread and it is less than 3.5 seconds or the test articles exhibit an average flame spread less than 3.5 seconds. Five replicates are to be tested if no flame spread is observed upon preliminary testing, if only 1 test article exhibits flame spread and it is equal to or greater than 3.5 seconds, or if the average flame spread is equal to or greater than 3.5 seconds. In accordance with the standard, 5 replicates were tested for this study. 3. Testing Sample Number：5 4. Sample Model: TFT-1091008001	Flammability of Textiles (s)	01	DNI
		02	DNI
		03	DNI
		04	DNI
		05	DNI

Note：

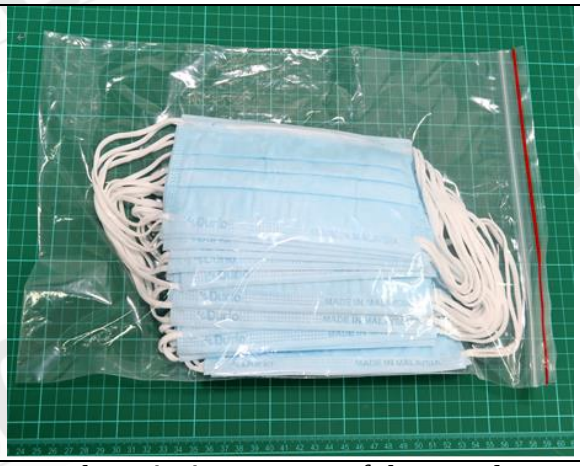
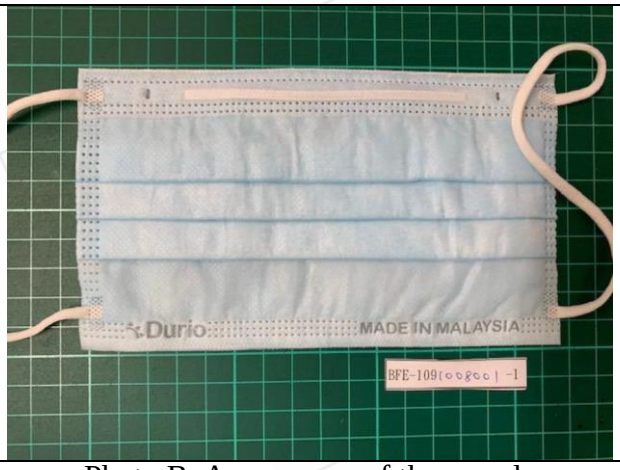
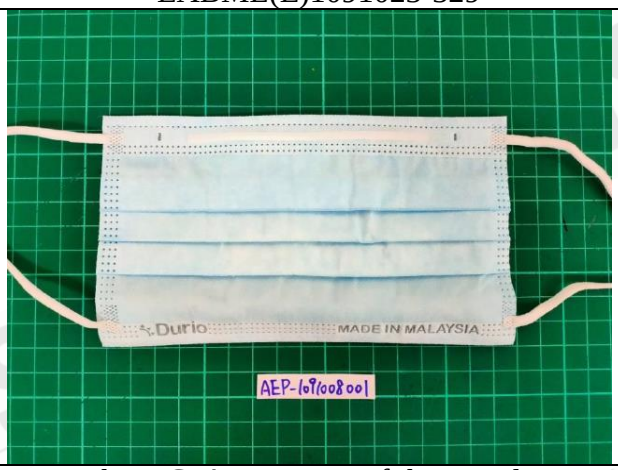
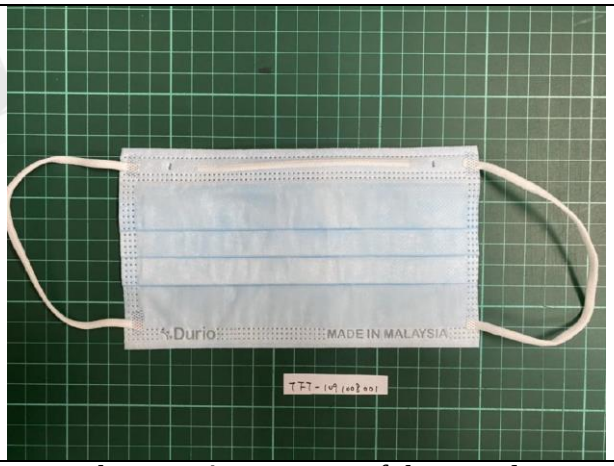
1. This test report is the test result issued by the testing institution as requested by the consignor.
2. DNI = Test Article did not ignite
3. Test Criteria for Specimen Classification (See 16 CFR Part 1610.7):

Class	Plain Surface Textile Fabric
1	Burn time ≧3.5 seconds
2	Not applicable to plain surface textile fabrics
3	Burn time <3.5 seconds

Note：

1. The test report merely reflects the test results of the consigned matters of the client and is not a certification
2. The content of this report is invalid if it is not presented as the entire report.

– Picture(s) –

<table>
<tr><td>  </td><td> 
</td></tr>
<tr><td>Photo A: Appearance of the sample
- EABML(E)1091023-329</td><td>Photo B: Appearance of the sample
- BFE-1091008001</td></tr>
<tr><td> 
</td><td> 
</td></tr>
<tr><td>Photo C: Appearance of the sample
- AEP-1091008001</td><td>Photo D: Appearance of the sample
- TFT-1091008001</td></tr>
</table>

---End of Report---