

INTERWORLD NETWORK (M) SDN BHD

G-11 & G-12, KOMPLEKS SEMPILAI, JALAN SEMPILAI, 13700 SEBERANG JAYA,
PENANG, MALAYSIA

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

Product Description: 3 PLY SURGICAL MASK

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

Test Requested: ISO 11737-1:2018(E)

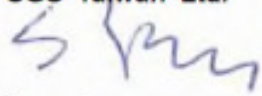
Test Method & Result: ---See following sheet(s)---

Date of Receipt: SEP. 26, 2020

Testing Period: SEP. 26, 2020 ~ OCT. 15, 2020

Note: This testing was performed by Europe America Biotechnology Co., Ltd.

Signed for and on behalf of
SGS Taiwan Ltd.


Sturm Su
Asst. Manager



Test Method & Result:**Test Article:**

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

Name: 3 Ply Surgical Mask

Lot No.: N/A

Model No.: N/A

Article No.: T-1090929-02

Purpose:

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

Materials:

Test Article: 3 Ply 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-Part1:
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	26	14	14
#2	38	30	135
#3	28	28	30
#4	20	18	24
#5	24	24	17
#6	22	22	32
#7	32	38	2
#8	18	12	10
#9	30	20	64
#10	150	118	18
Average (CFU/Sample)	38.8	32.4	34.6
*Average (CFU/g)	13.4 (CFU/g)	11.2 (CFU/g)	11.9 (CFU/g)
Negative control	0	0	0

- Remarks:
- 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.
 - < 3 = No organisms detected.
 - CFU = Colony Forming Units.
 - * = Average weight for single mask is 2.9 g; average (CFU/g) is obtained from average (CFU/Sample) ÷ 2.9 g.

Note :

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

TEST REPORT

Hardline Laboratory

Report No. : HL90579/2020

Page : 4 of 4

– Picture(s) –



Photo A: Appearance of the sample
- T-1090929-02

---End of Report---

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