

Hardline Laboratory

Report No. : HL50522/2020

Page : 1 of 5

Date : JUL. 28, 2020

### Formosa Energy-Carbon company Limited

No. 151, Yanzhou 2<sup>nd</sup> ST., Yongkang District, Tainan City 710, Taiwan (ROC)

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

Product Description: TWEC N95 MEDICAL Respirator  
Style/Item No.: CMK-1619  
Manufacturer/Vendor: Formosa Energy-Carbon company Limited  
Country of Origin: Taiwan

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

Test Requested:

1. ISO 11737-1:2018(E)
2. EN 14683:2019 Annex B
3. EN 14683:2019 Annex C
4. ISO 22609:2004

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

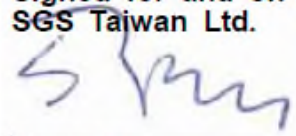
Date of Receipt : MAY 26, 2020

Testing Period : MAY 26, 2020 ~ JUL. 28, 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 14863:2019 Annex C and ISO 22609:2004 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 (E)**

##### Test Article:

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

Name: TWEC N95 Medical Respirator

Lot No.: N/A

Model No.: N/A

Article No.: T-1090528-01

##### Purpose:

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

##### Materials:

Test Article: TWEC N95 Medical Respirator

##### 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: Estimation of population of microorganisms on products.

##### Method:

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

Test article's packing was aseptically opened and cut into small pieces in the laminar flow hood and then transferred test article 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 0.45µm 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<br>(CFU/Sample) | Fungal<br>(CFU/Sample) | Anaerobic<br>(CFU/Sample) |
|----------------------|-------------------------|------------------------|---------------------------|
| #1                   | 86                      | 64                     | 10                        |
| #2                   | 46                      | 38                     | 58                        |
| #3                   | 24                      | 40                     | 10                        |
| #4                   | 208                     | 218                    | 206                       |
| #5                   | 52                      | 36                     | 10                        |
| #6                   | 116                     | 110                    | 30                        |
| #7                   | 62                      | 48                     | 22                        |
| #8                   | 24                      | 32                     | 26                        |
| #9                   | 28                      | 42                     | 16                        |
| #10                  | 358                     | 244                    | 36                        |
| Average (CFU/Sample) | 100.4                   | 87.2                   | 42.4                      |
| *Average (CFU/g)     | 19.3 (CFU/g)            | 16.8 (CFU/g)           | 8.2 (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 5.2 g; average (CFU/g) is obtained from average (CFU/Sample) ÷ 5.2 g.

**2. EN 14683:2019 Annex B:**

| Test Methods  | Test Item                               | Test Results |
|---|---|--------------|
| 1. Testing Sample Number: 5<br>2. Sample Dimensions : ~15.0 cm x ~21.5 cm<br>3. Test surface : Inside<br>4. Test Area: 49 cm <sup>2</sup><br>5. Flow rate during testing: 28.3 Liter/min<br>6. Counts of positive control: 1708 CFU<br>7. Counts of negative control: 0 CFU<br>8. Average size: 2.9 μm<br>9. Sample Model: BFE-1090528002 | 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 <sub>2</sub> O/cm <sup>2</sup> ) | Test Results (Pa/cm <sup>2</sup> ) |
|--|-----------------------|---|------------------------------------|
| 1. Testing Sample Number: 5<br>2. Test Flow Rate : 8.07 Liter/min<br>3. Pre-Conditioning: Minimum of 4 hours at (21±5) °C and (85±5) % relative humidity.<br>4. Sample Model: AEP-1090528002 | Differential pressure | 01  | 64.17                              |
|  |                       | 02  | 55.69                              |
|  |                       | 03  | 67.91                              |
|  |                       | 04  | 57.15                              |
|  |                       | 05  | 63.24                              |
|  |                       | Avg.  | 61.63                              |

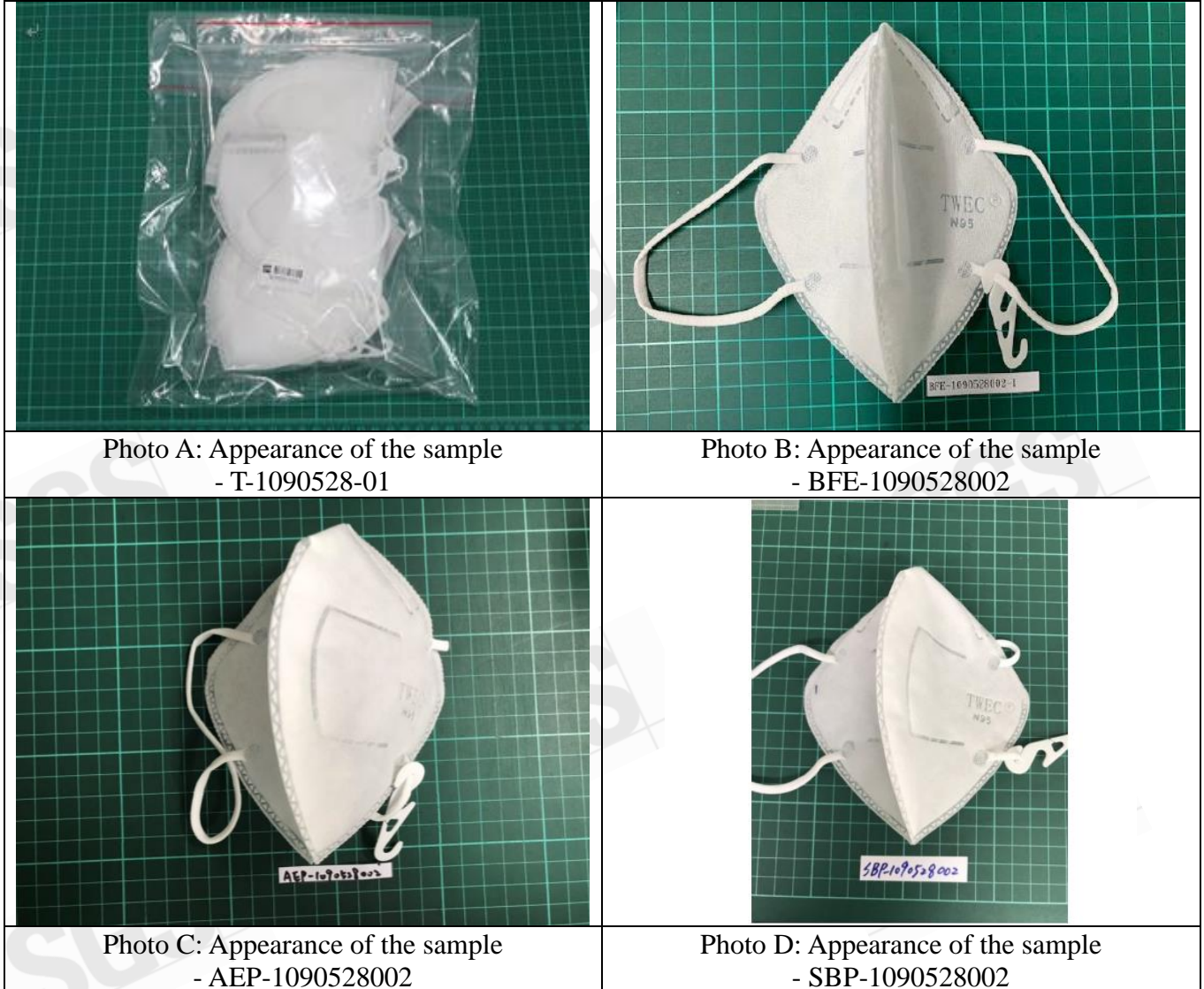
### 4. ISO 22609:2004

| Test Methods   | Test Item  | Test Article Number | Synthetic Blood Penetration |
|--|--|---------------------|-----------------------------|
| 1. Testing Sample Number: 32<br>2. Test Side: Outside<br>3. Pre-Conditioning : Minimum of 4 hours at (21±5) °C and (85±5) % relative humidity (RH)<br>4. Test Conditions : 26.7 °C and 43.6% RH<br>5. Sample Model: SBP-1090528002 | Synthetic Blood Penetration Resistance<br>120 mmHg (16.0 kPa)<br>As per client requested | 01-32               | Yes                         |

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.

– Picture(s) –



---End of Report---