

✓ Our company are registered IAF (1662066471)  
for ISO 13485,14001 ,45001 and 50001

**LINGHE** 

**MEDICAL FACE MASK**  
MADE IN TAIWAN

CE FDA

# BACKGROUND

Linghe industrial founded "Emma Enterprise" in 2016, and then in 2019, to improve the construction and design standards of air-conditioning projects, it was newly established as "Linghe International co. Ltd.". In 2020, we will expand the scope of services and set up a medical devices manufacture to provide the best products with excellent quality and professional attitude for customers.

The company has a professional team. During the manufacturing process, the specialized technicians strictly require and closely control, and uphold the professionalism to do the best. We look forward to taking a responsible and honest attitude, pursuing the concept of sustainable business and growth, and ensuring the highest quality to fulfill all expectations of customers.

# FUNCTION

## MB NON-WOVEN

- The melt-blown non-woven fabric is also known as the "heart of the mask", disperses the molten plastic through high-speed hot air, and spins the polymer melt through the spinneret of the ultra-fine nozzle, making it a high-performance melt-blown filter media.
- Unique electrostatic electret technology, bacteria, particles and droplets are being captured by its electrostatic adsorption.
- Exclusive nano zinc composite technology, inhibit the growth of bacteria.
- Effective filtering for dust, pollens, droplets and bacteria.
- Fiber fineness with an averaging below  $<5 \mu\text{m}$ .
- High porosity structure and small pore size to deliver outstanding filtration efficiency and low breathing resistance.
- Made of Polypropylene which is eco-friendly, biodegradable, non-toxic, non-irritating and light-weight.
- Available in blue ,black,orange,pink and green.

# SPECIFICATION/ STORAGE

- Content : 100% Polypropylene
- Classification : Melt-blown/Corona discharge
- Color : Blue ,black,orange,pink and green.
- Width : 175MM
- Basis Weight : 25GSM
- Customizable width and weight upon request.



## Storage Condition:

1. The best storage environment is below 20°C, it should not be placed in a high temperature/humidity environment, which will affect the electrostatic effect.
2. Avoid direct sunlight exposure.

# PACKING INSTRUCTION

## MB NON-WOVEN

- Length/roll : 1500M +/-5%
- Weight/roll : 6.5kg +/-5%
- Out. Diameter : 60cm +/-5%
- Inner Diameter of paper tube : 7.2cm
- Out. Diameter of paper tube : 8.4cm
- 3 Rolls per carton



# TESTING RESULT MB NON-WOVEN



# TESTING REPORT

## MB NON-WOVEN

**TTRI** 財團法人紡織產業綜合研究所  
Taiwan Textile Research Institute



Date: Oct.16,2020 Date of Receipt: Sep.24,2020 TEST REPORT TUCHENG COPY

Report No.: TAG91776 Quantity: 1PC (P1/5) Ref. No.: NIL  
Linghe International co. Ltd.(U3353) Mask

Report Title: \_\_\_\_\_ Item: \_\_\_\_\_  
No. 2, Gongyequ 40th Rd., Xitun Dist., Taichung City 407, Taiwan (R.O.C.)

Address: \_\_\_\_\_

| Test Items  |      | Test Results | Test Methods                                 |
|---|------|--------------|--|
| Sub-Micron Particulate<br>Filtration Efficiency(%)<br>(0.1 $\mu$ m PSL) | 1    | 98.68        | ASTM F2100-2019 9.3                          |
|   | 2    | 98.72        | ASTM F2299-2017                              |
|   | 3    | 98.66        | Flow rate:28.1                               |
|   | 4    | 98.72        | (Liter/min)                                  |
|   | 5    | 98.71        |  |
|   | Ave. | 98.70        |  |
| Air Exchange Pressure<br>(mmH <sub>2</sub> O/cm <sup>2</sup> )          | 1    | 3.7          | ASTM F2100-2019 9.2                          |
|   | 2    | 4.1          | EN 14683:2019 Annex C                        |
|   | 3    | 3.7          |  |
|   | 4    | 4.0          |  |
|   | 5    | 3.7          |  |
| Flammability<br>(as Received)   |      | DNI          | ASTM F2100-2019 9.5<br>CPSC 16 CFR 1610-2008 |

Note: 1mmH<sub>2</sub>O=9.8Pa.

Note: Air Exchange Pressure takes 5 masks for testing.

Note: Flammability takes 20 samples for testing.

Note: "DNI":Did Not Ignite.

Note: Sample description is given by the client: Linghe Medical Mask (Non-Sterile)

Note: The test report is the test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.

# TESTING REPORT

## MB NON-WOVEN

**TTRI** 財團法人紡織產業綜合研究所  
Taiwan Textile Research Institute



Date: Oct.16,2020 Date of Receipt: Sep.24,2020 TEST REPORT TUCHENG COPY

Report No.: TAG91776 Quantity: IPC Page Order/Pages: (P2/5) Ref. No.: NIL

Linghe International co. Ltd.(U3353) Mask

Report Title: \_\_\_\_\_ Item: \_\_\_\_\_

No. 2, Gongyequ 40th Rd., Xitun Dist., Taichung City 407, Taiwan (R.O.C.)

Address: \_\_\_\_\_

| Test Items                                      |    | Test Results | Test Methods        |
|---|----|--------------|---------------------|
| Synthetic Blood Penetration<br>Pressure:80 mmHg | 1  | None Seen    | ASTM F2100-2019 9.4 |
|   | 2  | None Seen    | ASTM F1862-2017     |
|   | 3  | None Seen    |                     |
|   | 4  | None Seen    |                     |
|   | 5  | None Seen    |                     |
|   | 6  | None Seen    |                     |
|   | 7  | None Seen    |                     |
|   | 8  | None Seen    |                     |
|   | 9  | None Seen    |                     |
|   | 10 | None Seen    |                     |
|   | 11 | None Seen    |                     |
|   | 12 | None Seen    |                     |
|   | 13 | None Seen    |                     |
|   | 14 | None Seen    |                     |
|   | 15 | None Seen    |                     |
|   | 16 | None Seen    |                     |

Note: Sample description is given by the client: Linghe Medical Mask (Non-Sterile)

Note: The test report is the test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.



# TESTING REPORT

## MB NON-WOVEN

**TTRI** 財團法人紡織產業綜合研究所  
Taiwan Textile Research Institute



Date: Oct. 16, 2020 Date of Receipt: Sep. 24, 2020 TEST REPORT TUCHENG COPY

Report No.: TAG91776 Quantity: IPC (P3/5) Ref. No.: NIL  
Linghe International co. Ltd.(U3353) Mask

Report Title: \_\_\_\_\_ Item: \_\_\_\_\_  
No. 2, Gongyequ 40th Rd., Xitun Dist., Taichung City 407, Taiwan (R.O.C.)

Address: \_\_\_\_\_

| Test Items                                      |           | Test Results | Test Methods        |
|---|-----------|--------------|---------------------|
| Synthetic Blood Penetration<br>Pressure:80 mmHg | 17        | None Seen    | ASTM F2100-2019 9.4 |
|   | 18        | None Seen    | ASTM F1862-2017     |
|   | 19        | None Seen    |                     |
|   | 20        | None Seen    |                     |
|   | 21        | None Seen    |                     |
|   | 22        | None Seen    |                     |
|   | 23        | None Seen    |                     |
|   | 24        | None Seen    |                     |
|   | 25        | None Seen    |                     |
|   | 26        | None Seen    |                     |
|   | 27        | None Seen    |                     |
|   | 28        | None Seen    |                     |
|   | 29        | None Seen    |                     |
|   | 30        | None Seen    |                     |
| 31  | None Seen |              |                     |
| 32  | None Seen |              |                     |

Note: Sample description is given by the client: Linghe Medical Mask (Non-Sterile)

Note: The test report is the test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.

# TESTING REPORT

## MB NON-WOVEN

**TTRI** 財團法人紡織產業綜合研究所  
Taiwan Textile Research Institute



Date: Oct. 16, 2020 Date of Receipt: Sep. 24, 2020 TEST REPORT TUCHENG COPY

Report No.: TAG9I776 Quantity: IPC Page Order/Pages: (P4/5) Ref. No.: NIL

Report Title: Linghe International co. Ltd.(U3353) Item: Mask

Address: No. 2, Gongyequ 40th Rd., Xitun Dist., Taichung City 407, Taiwan (R.O.C.)

| Test Items            |   | Test Results | Test Methods        |
|-----------------------|---|--------------|---------------------|
| Bacterial Filtration  | 1 | 99.8         | ASTM F2100-2019 9.1 |
| Efficiency (BFE)(%)   | 2 | 99.6         | ASTM F2101-2019     |
| Staphylococcus aureus | 3 | 99.6         |                     |
| ATCC 6538             | 4 | 99.7         |                     |
|                       | 5 | 99.8         |                     |

Note: Control average: 2407 CFU.

Note: Mean particle size: 2.9  $\mu\text{m}$ .

Note: Testing side: outside of specimen.

Note: Testing area: 39.5 cm<sup>2</sup>.

Note: Flow rate : 28.3 L/min.

Note: Sample description is given by the client: Linghe Medical Mask (Non-Sterile)

Note: The test report is the test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.



- Professional & Qualified Manufacturer
- ISO13485 Approved Quality Management System Standard
- Uphold integrity and honesty to elevate customer value.
- Continuous improvement and optimization through production
- Monthly capacity over 30 million pcs
- FDA No. 50306263
- D-U-N-S No. 65-918-0554

The screenshot shows the FDA's Establishment Registration & Device Listing page. The header includes the U.S. Department of Health & Human Services logo, the FDA logo, and the text 'U.S. FOOD & DRUG ADMINISTRATION'. There are navigation tabs for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. The main content area is titled 'Establishment Registration & Device Listing' and includes a search bar and a 'New Search' button. The search results for 'LING HE INTERNATIONAL CO. LTD.' are displayed, with the following information highlighted in red boxes: 'Owner/Operator: Linghe International Co. Ltd.', 'Owner/Operator Number: 17079446', and 'Official Correspondent: Jie Li'. The page also includes a 'U.S. Agent' section with contact information for Howard Huang.

The screenshot shows the FDA DUNS Portal page. The header includes the U.S. Department of Health & Human Services logo, the FDA logo, and the text 'U.S. FOOD & DRUG ADMINISTRATION'. The page is titled 'FDA DUNS Portal' and includes a search bar and a 'Logout' button. The main content area is titled 'FDA DUNS Portal' and includes a search bar and a 'Logout' button. The search results for 'LING HE INTERNATIONAL CO. LTD.' are displayed, with the following information highlighted in red boxes: 'DUNS Number: 65-918-0554', 'Facility Name: LING HE INTERNATIONAL INDUSTRIAL CO., LTD.', 'Street Address: No. 3, Jingmao 8th Rd., Gangwei VII', 'City: Taichung City', 'Zip/Postal Code: 40761', 'Country Code (ISO 2): TW', and 'Country Name: Taiwan'. The page also includes a 'Helpful Links' section with links to 'Quick User Guide', 'Step-by-Step Instruction Guide', 'ACE/ITDS Industry Information', and 'FDA Contact Information'.

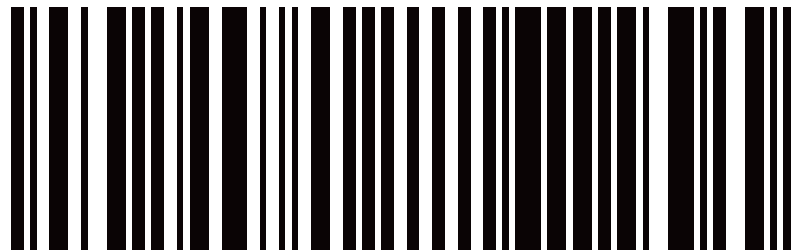
# MEDICAL FACE MASK



3-PLY non-woven fabric provides greatest protection over droplet, bacteria and pollutant.

# SPECIFICATION/ PACKAGING

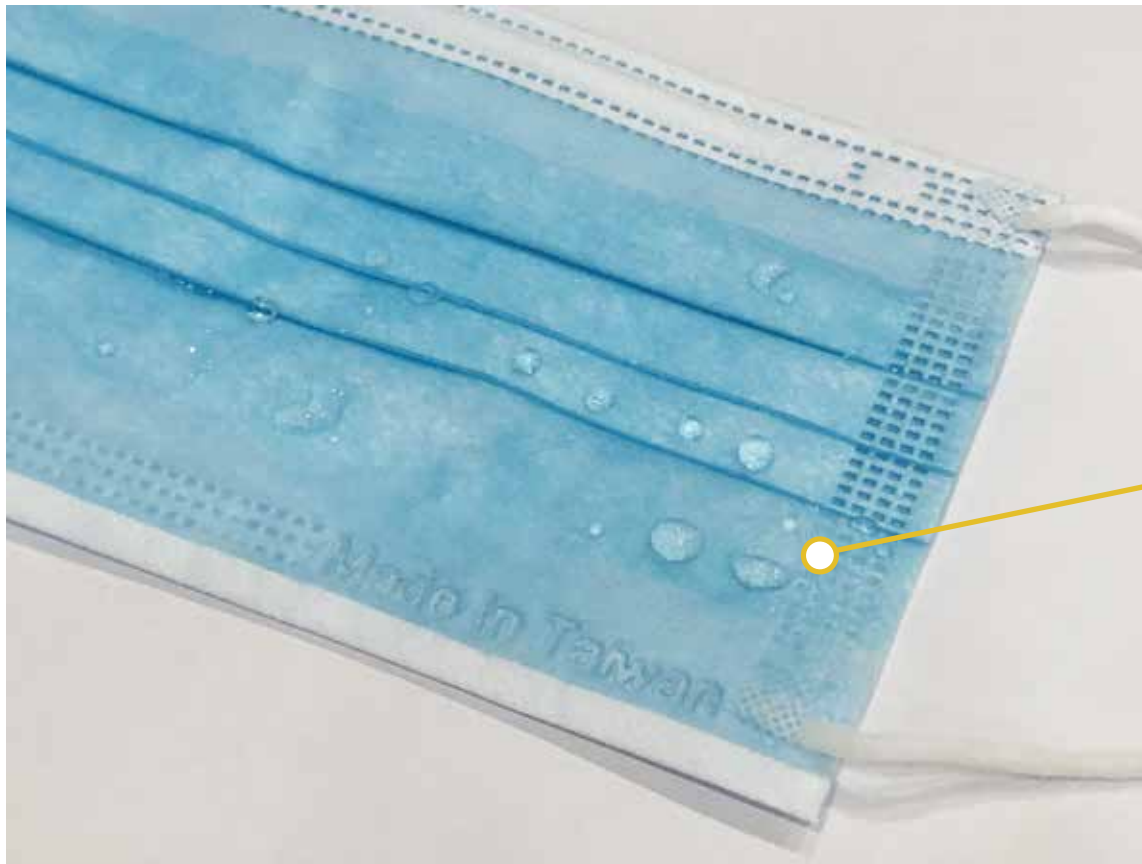
- ▲ Style: Adult
- ▲ Type: Flat
- ▲ Size: 17.5 cm X 9.5 cm  $\pm$ 0.5 cm
- ▲ Quantity: 50 PCS/BOX, 40 BOXES/CARTON
- ▲ Validity: 5 YEARS
- ▲ Barcode:



4719881700027

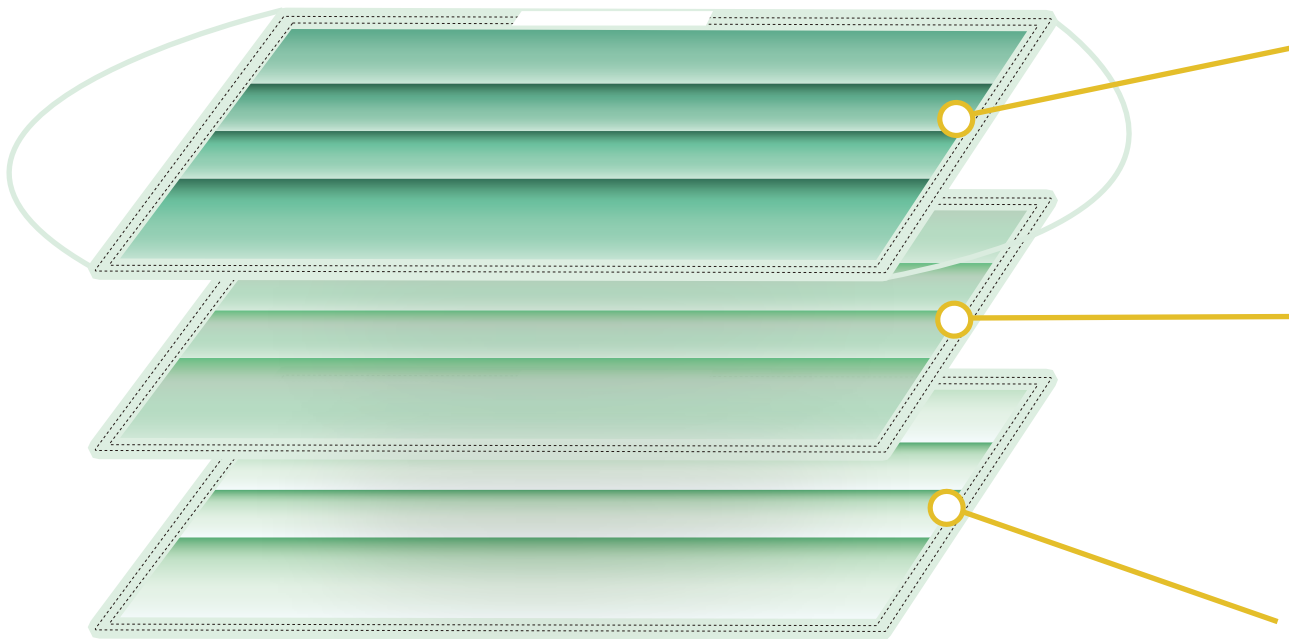
# FUNCTION FACE MASK

High density structure with waterrepellent function, which prevent droplet and moisture penetration.



Non-Absorbency

# MEDICAL FACE MASK



## Outer layer

Water-repellent  
non-woven fabric  
Polypropylene

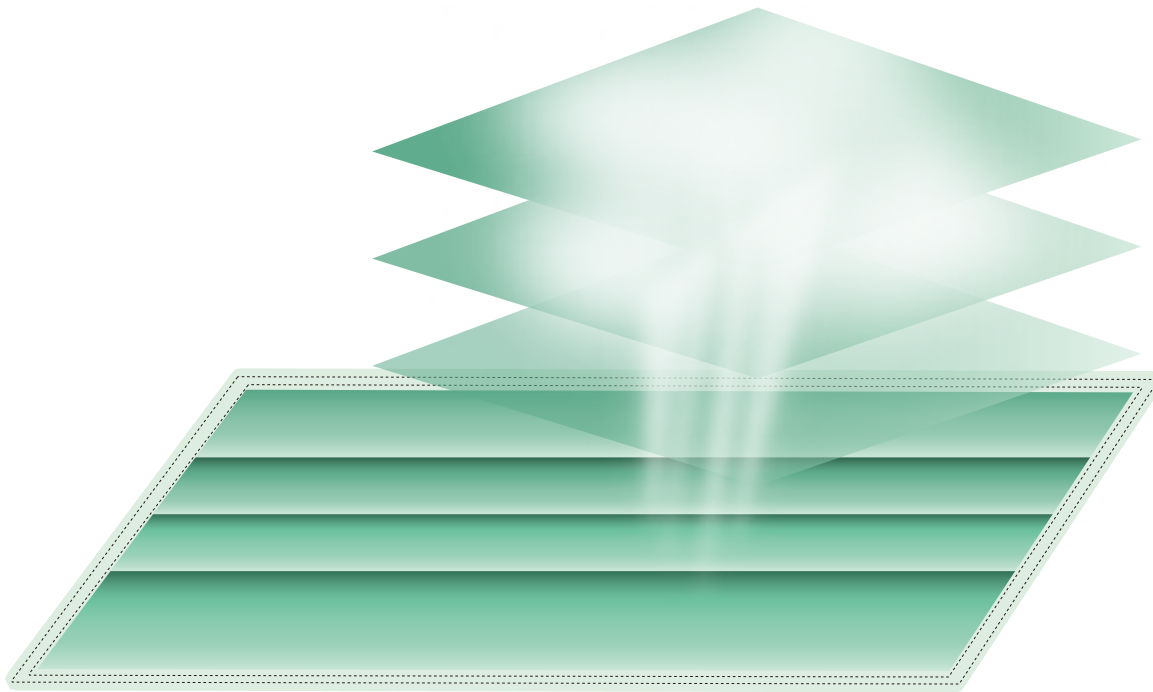
## Filter layer

Nano Zinc Composite  
Melt-blown  
non-woven fabric

## Inner layer

Hydrophilic non-woven  
Polypropylene/Polyethylene

# MEDICAL FACE MASK



▲ Bacterial Filtration  
Efficiency (BFE)

99% above

▲ Particle Filtration  
Efficiency (PFE)

95% above

Exclusive nano zinc composite non-woven,  
inhibit the growth of bacteria.



# VARIETY



- Purple
- Purple
- Yellow
- Orange
- Orange
- Pink
- Black
- Green
- Blue

# FUNCTION FACE MASK

▲ Ultrasonic edges to prevent from dust/bacteria entering.



▲ Adjustable nosepiece and form-fitting design.

▲ Soft expandable ear-loop without pulling and irritation.



# TESTING REPORT FACE MASK

**TTRI** 財團法人紡織產業綜合研究所  
Taiwan Textile Research Institute



TEST REPORT TUCHENG

Date: Oct.16,2020 Date of Receipt: Sep.24,2020

Report No.: TFF91774 Quantity: 1PC Page Order/Pages: (P1/3) Ref. No.: NIL

Report Title: Linghe International co. Ltd.(U3353) Item: Mask

Address: No. 2, Gongyequ 40th Rd., Xitun Dist., Taichung City 407, Taiwan (R.O.C.)

| Test Items  |   | Test Results | Test Methods             |
|---|---|--------------|--------------------------|
| Air Exchange Pressure<br>(mmH2O/cm <sup>2</sup> ) | 1 | 4.0          | CNS 14774 T5017-2018 9.4 |
|   | 2 | 3.8          | CNS 14777 T4039-2003     |
|   | 3 | 3.7          |                          |
|   | 4 | 3.8          |                          |
|   | 5 | 4.0          |                          |

Note: Air Exchange Pressure takes 5 masks for testing.

Note: Sample description is given by the client: Linghe Medical Mask (Non-Sterile)

Note: The test report is the test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.

# TESTING REPORT FACE MASK

**TTRI** 財團法人紡織產業綜合研究所  
Taiwan Textile Research Institute



TEST REPORT TUCHENG

Date: Oct.16.2020 Date of Receipt: Sep.24,2020

Report No.: TFF91774 Quantity: 1PC Page Order/Pages: (P2/3) Ref. No.: NIL

Report Title: Linghe International co. Ltd.(U3353) Item: Mask

Address: No. 2, Gongyequ 40th Rd., Xitun Dist., Taichung City 407, Taiwan (R.O.C.)

| Test Items            |   | Test Results | Test Methods             |
|-----------------------|---|--------------|--------------------------|
| Bacterial Filtration  | 1 | 99.8         | CNS 14774-T5017-2018 9.2 |
| Efficiency (BFE)(%)   | 2 | 99.5         | CNS 14775 T4037-2003     |
| Staphylococcus aureus | 3 | 99.5         |                          |
| ATCC 6538             | 4 | 99.6         |                          |
|                       | 5 | 99.7         |                          |

Note: Control average: 2407 CFU.

Note: Mean particle size: 2.9  $\mu\text{m}$ .

Note: Testing side: outside of specimen.

Note: Testing area: 39.5 cm<sup>2</sup>.

Note: Flow rate : 28.3 L/min.

Note: Sample description is given by the client: Linghe Medical Mask (Non-Sterile)

Note: The test report is the test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.

# TESTING REPORT FACE MASK

黃玉娟#21 (04-24269527)

**TTRI** 財團法人紡織產業綜合研究所  
Taiwan Textile Research Institute



試驗報告 土城場區  
TEST REPORT TUCHENG

發行日期 Date of Issue: 2020.11.24 收件/試驗起始日期 Date of Receipt and Test Start: 2020.11.04

報告編號 Report No.: TFF9K076 數量 Quantity: 1件 報告頁次/頁數 Page Order/Pages: (P1/6) 來文字號 Ref. No.: 空白

報告抬頭 Report Title: 令和國際實業股份有限公司(U3353) 試件類別 Item: 口罩

地址 Address: 407 台中市西屯區工業區四十路2號

| 試驗項目                            |   | 試驗結果 | 試驗方法                  |
|---------------------------------|---|------|-----------------------|
| 空氣交換壓力<br>(Pa/cm <sup>2</sup> ) | 1 | 29.5 | EN 14683:2019 Annex C |
|                                 | 2 | 28.7 |                       |
|                                 | 3 | 28.3 |                       |
|                                 | 4 | 28.2 |                       |
|                                 | 5 | 29.5 |                       |

註：依委託者所提供來樣資料為：令和醫療口罩（未滅菌）

本試驗報告僅供參考  
不做任何正式文件證明用

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# TESTING REPORT FACE MASK

**TTRI** 財團法人紡織產業綜合研究所  
Taiwan Textile Research Institute



黃玉娟#21 (04-24269527)

試驗報告 土城場區  
TEST REPORT TUCHENG

發行日期 2020.11.24 收件/試驗起始日期 2020.11.04  
Date of Issue: 2020.11.24 Date of Receipt and Test Start: 2020.11.04

報告編號 TFF9K076 數量 1件 報告頁次/頁數 (P2/6) 來文字號 空白  
Report No.: TFF9K076 Quantity: 1件 Page Order/Pages: (P2/6) Ref. No.: 空白

報告抬頭 令和國際實業股份有限公司(U3353) 試件類別 口罩  
Report Title: 令和國際實業股份有限公司(U3353) Item: 口罩

地址 407 台中市西屯區工業區四十路2號  
Address: 407 台中市西屯區工業區四十路2號

| 試驗項目                              |    | 試驗結果 | 試驗方法                     |
|-----------------------------------|----|------|--------------------------|
| 合成血液穿透性<br>壓力:120 mmHg (16.0 kPa) | 1  | 無穿透  | EN 14683:2019            |
|                                   | 2  | 無穿透  | ISO 22609:2004           |
|                                   | 3  | 無穿透  | 本試驗報告僅供參考<br>不做任何正式文件證明用 |
|                                   | 4  | 無穿透  |                          |
|                                   | 5  | 無穿透  |                          |
|                                   | 6  | 無穿透  |                          |
|                                   | 7  | 無穿透  |                          |
|                                   | 8  | 無穿透  |                          |
|                                   | 9  | 無穿透  |                          |
|                                   | 10 | 無穿透  |                          |
|                                   | 11 | 無穿透  |                          |
|                                   | 12 | 無穿透  |                          |
|                                   | 13 | 無穿透  |                          |
|                                   | 14 | 無穿透  |                          |
|                                   | 15 | 無穿透  |                          |
|                                   | 16 | 無穿透  |                          |

註：依委託者所提供來樣資料為：令和醫療口罩（未滅菌）

# TESTING REPORT FACE MASK

**TTRI** 財團法人紡織產業綜合研究所  
Taiwan Textile Research Institute



真玉網#21 (U4-24269527)

試驗報告 土城場區  
TEST REPORT TUCHENG

發行日期 Date of Issue: 2020.11.24 收件/試驗起始日期 Date of Receipt and Test Start: 2020.11.04  
 報告編號 Report No.: TFF9K076 數量 Quantity: 1件 報告頁次/頁數 Page Order/Pages: (P3/6) 來文字號 Ref. No.: 空白  
 報告抬頭 Report Title: 令和國際實業股份有限公司(U3353) 試件類別 Item: 口罩  
 地址 Address: 407 台中市西屯區工業區四十路2號

| 試驗項目                              | 試驗結果 | 試驗方法 |
|-----------------------------------|------|------|
| 合成血液穿透性<br>壓力:120 mmHg (16.0 kPa) | 17   | 無穿透  |
|                                   | 18   | 無穿透  |
|                                   | 19   | 無穿透  |
|                                   | 20   | 無穿透  |
|                                   | 21   | 無穿透  |
|                                   | 22   | 無穿透  |
|                                   | 23   | 無穿透  |
|                                   | 24   | 無穿透  |
|                                   | 25   | 無穿透  |
|                                   | 26   | 無穿透  |
|                                   | 27   | 無穿透  |
|                                   | 28   | 無穿透  |
|                                   | 29   | 無穿透  |
| 30                                | 無穿透  |      |
| 31                                | 無穿透  |      |
| 32                                | 無穿透  |      |

本試驗報告僅供參考  
不做任何正式文件證明用

註: 依委託者所提供來樣資料為: 令和醫療口罩 (未滅菌)

# TESTING REPORT FACE MASK

**TTRI** 財團法人紡織產業綜合研究所  
Taiwan Textile Research Institute



黃玉娟#21 (04-24269527)

試驗報告 土城場區  
TEST REPORT TUCHENG

發行日期 Date of Issue: 2020.11.24 收件/試驗起始日期 Date of Receipt and Test Start: 2020.11.04

報告編號 Report No.: TFF9K076 數量 Quantity: 1件 報告頁次/頁數 Page Order/Pages: (P4/6) 來文字號 Ref. No.: 空 白

報告抬頭 Report Title: 令和國際實業股份有限公司(U3353) 試件類別 Item: 口罩

地址 Address: 407 台中市西屯區工業區四十路2號

| 試驗項目              |   | 試驗結果 | 試驗方法                |
|-------------------|---|------|---------------------|
| 微生物潔淨性<br>(cfu/g) | 1 | 15.7 | EN 14683:2019       |
|                   | 2 | 18.3 | EN ISO 11737-1:2018 |
|                   | 3 | 15.4 |                     |
|                   | 4 | 17.9 |                     |
|                   | 5 | 11.7 |                     |

註：依委託者所提供來樣資料為：令和醫療口罩（未滅菌）

本試驗報告僅供參考  
不做任何正式文件證明用



# TESTING REPORT FACE MASK

黃玉娟#21 (04-24269527)

**TTRI** 財團法人紡織產業綜合研究所  
Taiwan Textile Research Institute



試驗報告 土城場區  
TEST REPORT TUCHENG

發行日期 Date of Issue: 2020.11.24 收件/試驗起始日期 Date of Receipt and Test Start: 2020.11.04  
報告編號 Report No.: TFF9K076 數量 Quantity: 1件 報告頁次/頁數 Page Order/Pages: (P5/6) 來文字號 Ref. No.: 空白  
報告抬頭 Report Title: 令和國際實業股份有限公司(U3353) 試件類別 Item: 口罩  
地址 Address: 407 台中市西屯區工業區四十路2號

| 試驗項目      | 試驗結果   | 試驗方法                  |
|-----------|--------|-----------------------|
| 細菌過濾效率(%) | 1 99.4 | EN 14683:2019 Annex B |
| 金黃色葡萄球菌   | 2 99.7 |                       |
| ATCC 6538 | 3 99.2 |                       |
|           | 4 99.5 |                       |
|           | 5 99.4 |                       |

註：對照組的平均菌落數：1835 CFU。

註：平均粒徑：3.2  $\mu\text{m}$ 。

註：測試面：外側。

註：測試面積：39.5  $\text{cm}^2$

註：測試流量：28.3 L/min。

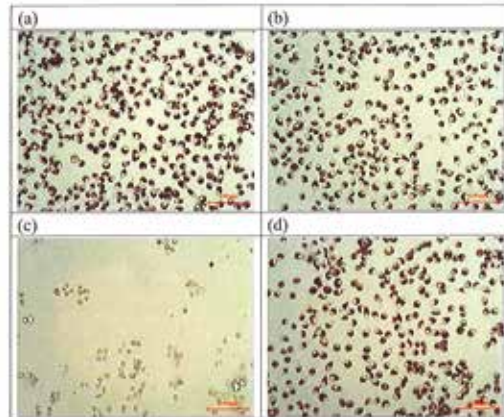
註：依委託者所提供來樣資料為：令和醫療口罩（未滅菌）

本試驗報告僅供參考  
不做任何正式文件證明用

# TESTING REPORT FACE MASK



FINAL REPORT Report No.: MSC-202009-030-CE-R01



**Figure 1.** The observed cell morphology of L929 cells after being treated for 24 h under 100X inverted microscope.

- a. Blank (B): culture medium
- b. Negative control (NC): HDPE
- c. Positive control (PC): 10% DMSO
- d. Test sample (S): LINGHE MEDICAL FACE MASK (Non-sterile)



FINAL REPORT Report No.: MSC-202009-030-CE-R01

## Appendix I. Qualitative morphological grading of cytotoxicity

| Grade | Reactivity | Conditions of all cultures  |
|-------|------------|---|
| 0     | None       | Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth  |
| 1     | Slight     | Not more than 20% of the cells are round, loosely attached and without intracytoplasmic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition is observed. |
| 2     | Mild       | Not more than 50% of the cells are round, devoid of intracytoplasmic granules; not more than 50% growth inhibition is observed.   |
| 3     | Moderate   | Not more than 70% of the cell layers contain rounded cells or are lysed; cell layers not completely destroyed, but more than 50% growth inhibition is observed.   |
| 4     | Severe     | Nearly complete or complete destruction of the cell layers.   |

# TESTING REPORT FACE MASK



FINAL REPORT Report No.: MSC-202009-030-CE-R01

## QUALITY ASSURANCE STATEMENT

The Quality Assurance personnel had inspected the conduct of different phases of the study according to a predetermined study schedule. To the best of our knowledge, there were no deviations from the study plan and standard operating procedures that would affect the integrity of this study. This report has been audited by the QA personnel in accordance with the appropriate standard operating procedures of Master Laboratory Co., Ltd. described the methods and procedures used in the study, and the reported results accurately reflect the raw data generated during this study. Listed below are the phases in this study that were audited by the QA personnel and the dates the audits were performed and findings reported to facility management (FM).

### Inspection record:

| Date of inspection | Phase  | Date Reported to SD | Date Reported to FM |
|--------------------|--|---------------------|---------------------|
| 09.23.2020         | Study protocol, Personnel quality and test article. (Study base)     | 09.23.2020          | 09.23.2020          |
| 09.29.2020         | Date of dosing. (Process base)                                       | 09.29.2020          | 09.29.2020          |
| 09.30.2020         | Environment, equipment, and SOP. (Facility base)                     | 09.30.2020          | 09.30.2020          |
| 09.30.2020         | Study system, study report, raw data, and final report. (Study base) | 09.30.2020          | 09.30.2020          |

### Quality Assurance unit in charge

Ying Chun Chen  
Ying Chun Chen

10-31-2020  
Date



FINAL REPORT Report No.: MSC-202009-030-CE-R01



Table 1. Cytotoxicity evaluated using neutral red stain

| Test item               | Cell lysis (%) | Grade |
|-------------------------|----------------|-------|
| Blank (B)               | 0              | 0     |
| Negative control (NC)   | 0              | 0     |
| Positive control (PC)   | 100            | 4     |
| Test sample extract (S) | 0              | 0     |

Table 2. The results of MTT assay for evaluation of cell viability

| Test Item               | Absorbance (OD <sub>570 nm</sub> ) | Viability (%) | Mortality (%) |
|-------------------------|------------------------------------|---------------|---------------|
| Blank (B)               | 0.527±0.027                        | 100           | 0             |
| Negative control (NC)   | 0.502±0.041                        | 95            | 5             |
| Positive control (PC)   | 0.069±0.001                        | 13            | 87            |
| Test sample extract (S) | 0.428±0.014                        | 81            | 19            |
| 50% test sample extract | 0.447±0.042                        | 85            | 15            |

# TESTING REPORT FACE MASK

Report No.: S20121503202E   page 1 of 3

## Test Report

**Applicant:** Linghe International co. Ltd.  
**Address:** No. 3, Jingmao 8th Rd., Xitun Dist., Taichung City 407013, Taiwan (R.O.C.)

**The following sample(s) was/were submitted and identified on behalf of the client as:**

**Product name:** Mask  
**Model:** Best-01  
**Brand:** Linghe  
**Manufacturer:** Linghe International co. Ltd.  
**Address:** No. 3, Jingmao 8th Rd., Xitun Dist., Taichung City 407013, Taiwan (R.O.C.)  
**Classification:** Level 3 barrier  
**Product lot:** 3 non-consecutive lots (lot1-Nov18, lot2-Nov20, Lot3 Nov23) each working day produce 60000 Pcs to 100k Pcs (Nov working lots as Nov2/3/4/5/6/7/8/10/11/12/13/14/16/17/18/19/20/21/23/24/25/26/27/30)  
**Sample quantity:** 200 Pcs for three non-consecutive lots total 600 Pcs


**Sample Received Date:** Dec. 15, 2020  
**Testing Period:** Dec. 15, 2020- Dec. 28, 2020

**Test Requirement:**  
 According to the requirement of the client, the test item(s) of the sample is according to the standard ASTM F2100-2019.

**Test Result(s):** Please refer to the following page(s)

**Test Method:** Please refer to the following page(s)

Compiled by: \_\_\_\_\_  
 Reviewed by: \_\_\_\_\_  
 Date: \_\_\_\_\_



SHENZHEN WAS TECHNOLOGY CO., LTD. / F. BUILDING B. FENDA SCIENCE PARK, SANWEI COMMUNITY, XIGANG STREET SHENZHEN 518126, PEOPLE'S REPUBLIC OF CHINA

Report No.: S20121503202E page 2 of 3

### Summary of assessment\*

| Items  | Test Methods | Q / lots | Lots | Total | Assessment |
|--|--------------|----------|------|-------|------------|
| Resistance to Penetration by Synthetic Blood | ASTM F1862   | 32       | 3    | 96    | Pass       |
| Total  | N/A          | 32       | /    | 96    | /          |

**Key**

|      |  |
|------|--|
| Pass | Requirement satisfied.   |
| NRq  | The clauses were not required.   |
| Fail | Requirement not satisfied. Refer to the "Result details" section for more information. |
| N.A. | Requirement not applicable.  |

\* Assessment relates only to those specimens which were tested and are the subject of this report.

**Test Result(s):**

Summary: This 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 14883:2019 and AS4381:2015) 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±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. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.


Number of Test Articles Tested : 96  
 Number of Test Articles Passed : 96  
 Test Site : Outside  
 Pre-Conditioning : Minimum of 4 hours at 21 ± 5 °C and 85 ± 5 % relative humidity (RH)  
 Test Conditions : 22.3 °C and 81% RH  
 Results: Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show passing results.  
 Test Pressure: 180 mmHg (21.3 kPa)

SHENZHEN WAS TECHNOLOGY CO., LTD. / F. BUILDING B. FENDA SCIENCE PARK, SANWEI COMMUNITY, XIGANG STREET SHENZHEN 518126, PEOPLE'S REPUBLIC OF CHINA

# CERTIFICATION



**衛生福利部第一等級醫療器材許可證**  
衛部醫器製壹字第 008741 號



中文名稱：令和醫療口罩(未滅菌)

英文名稱：LINGHE Medical Face Mask (Non-Sterile)

類別：第 1 類：一般及整型外科手術製 藥商名稱： 令和國際實業股份有限公司

規格：成人平面、兒童平面、以下空白。 製造廠名稱：令和國際實業股份有限公司

製造廠地址：臺中市西屯區工業區四十路  
2 號

效能：限醫療器材管理辦法「醫療用衣物(I.4040)」第一等級鑑別範圍。

處方：空白

前項醫療器材經本部審核與藥事法之規定相符應發給許可證以資證明

衛生福利部部長

**陳時中**

發證日期 109 年 12 月 17 日  
有效日期 114 年 12 月 17 日

|                       |       |       |       |       |       |
|-----------------------|-------|-------|-------|-------|-------|
| 檢<br>查<br>基<br>礎<br>查 |       |       |       |       |       |
| 日期                    | 年 月 日 | 年 月 日 | 年 月 日 | 年 月 日 | 年 月 日 |
| 文號                    |       |       |       |       |       |

MK 016749

# CERTIFICATION

中華民國

中市藥販 字第 6203279678 號

## 販賣業藥商許可執照

藥商名稱：令和國際事業股份有限公司  
地址：臺中市西屯區龍興八路3號

負責人：趙麗玲

上開藥商依照藥事法第二十七條之規定發給許可執照

局長 曾梓展

中華民國109年08月13日

| 營業項目 | 管理人姓名 | 管理人身份 | 記 | 事 |
|------|-------|-------|---|---|
| 醫療器材 |       |       |   |   |
|      |       |       |   |   |
|      |       |       |   |   |

中華民國

中市藥製 字第 6103270217 號

## 製造業藥商許可執照

藥商名稱：令和國際實業股份有限公司  
地址：臺中市西屯區工業區四十路2號

負責人：趙麗玲

上開藥商依照藥事法第二十七條之規定發給許可執照

衛生福利部

中華民國109年09月15日

| 營業項目 | 監製人姓名 | 監製人身份 | 記 | 事  |
|------|-------|-------|---|--|
| 醫療器材 |       |       |   | 醫療器材(102) 醫療器材<br>原料(10209) 其他醫療器<br>材及原料(1) |
|      |       |       |   |  |
|      |       |       |   |  |



# REGISTRATION

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## Establishment Registration & Device Listing

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|   |   |
|---|---|
| <b>Proprietary Name:</b>                | Baokumo Mask; BOLE Mask; Brest Mask; Careyou Mask; HE RUN Mask; HONG ZHUN Mask; HuangChau Hospital Mother Mask; IDR Mask; JIN HONG Mask; JUN TING Mask; LINGHE Medical face mask; Singfa Mask; Sunforest Mask; Universal Mask; Whole Mask; XIN CHUAN Mask; YU CHUN Mask |
| <b>Classification Name:</b>             | FACE MASK (EXCEPT N95 RESPIRATOR) FOR GENERAL PUBLIC/HEALTHCARE PERSONNEL PER IIE GUIDANCE  |
| <b>Product Code:</b>                    | <b>QKR</b>  |
| <b>Device Class:</b>                    | Not Classified  |
| <b>Registered Establishment Name:</b>   | <a href="#">LINGHE INTERNATIONAL CO. LTD.</a>   |
| <b>Registered Establishment Number:</b> | 3017812380  |
| <b>Owner/Operator:</b>                  | <a href="#">Linghe International co. Ltd.</a>   |
| <b>Owner/Operator Number:</b>           | 10078445  |
| <b>Establishment Operations:</b>        | Contract Manufacturer; Foreign Exporter; Manufacturer; Specification Developer  |

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|   |  |
|---|--|
| <b>Proprietary Name:</b>                | Careyou Surgical Mask EUA Authorized; HuangMother Hospital Medical Face Mask EUA Authorized; LINGHE Medical Face Mask EUA Authorized |
| <b>Classification Name:</b>             | MASK, SURGICAL, EUA AUTHORIZED   |
| <b>Product Code:</b>                    | <b>QMF</b>   |
| <b>Device Class:</b>                    | Not Classified   |
| <b>Registered Establishment Name:</b>   | <a href="#">LINGHE INTERNATIONAL CO. LTD.</a>  |
| <b>Registered Establishment Number:</b> | 3017812380   |
| <b>Owner/Operator:</b>                  | <a href="#">Linghe International co. Ltd.</a>  |
| <b>Owner/Operator Number:</b>           | 10078445   |
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## Establishment Registration & Device Listing

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|   |  |
|---|--|
| <b>Proprietary Name:</b>                | Careyou Respirator; LINGHE Respirator                        |
| <b>Classification Name:</b>             | RESPIRATOR, SURGICAL   |
| <b>Product Code:</b>                    | <b>MSH</b>   |
| <b>Device Class:</b>                    | 2  |
| <b>Regulation Number:</b>               | 878.4040   |
| <b>Medical Specialty:</b>               | General & Plastic Surgery                                    |
| <b>Registered Establishment Name:</b>   | <a href="#">LINGHE INTERNATIONAL CO. LTD.</a>                |
| <b>Registered Establishment Number:</b> | 3017812380   |
| <b>Owner/Operator:</b>                  | <a href="#">Linghe International co. Ltd.</a>                |
| <b>Owner/Operator Number:</b>           | 10078445   |
| <b>Establishment Operations:</b>        | Contract Manufacturer; Manufacturer; Specification Developer |

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|                                  |  |
|----------------------------------|--|
| Proprietary Name:                | LINGHE Medical face mask   |
| Classification Name:             | MASK, SURGICAL   |
| Product Code:                    | <b>FXX</b>   |
| Device Class:                    | 2  |
| Regulation Number:               | 878.4040   |
| Medical Specialty:               | General & Plastic Surgery  |
| Registered Establishment Name:   | <a href="#">LINGHE INTERNATIONAL CO. LTD.</a>                                  |
| Registered Establishment Number: | 3017812380   |
| Owner/Operator:                  | <a href="#">Linghe International co. Ltd.</a>                                  |
| Owner/Operator Number:           | 10078445   |
| Establishment Operations:        | Contract Manufacturer; Foreign Exporter; Manufacturer; Specification Developer |

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## DECLARATION OF CONFORMITY Regarding Medical Device Regulation (EU) 2017/745

**Manufacturer:** Linghe International co. Ltd.  
**Address:** No. 3, Jingmao 8th Rd., Xitun Dist., Taichung City 407013,  
Taiwan (R.O.C.)

**EC Representative:** SUNGO Europe B.V.  
**Address:** Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

**Product Name:** LINGHE Medical Face Mask (Non-Sterile)  
**Model:** TW-best01

**Classification:** Class I  
**Rule:** Rule 1, Annex VIII, Regulation (EU) 2017/745  
**Conformity Assessment:** Annex II+III of Regulation (EU) 2017/745

**Procedure:**  
**SRN:** /  
**Basic UDI-DI:** /

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the following harmonized standards.

|                                |                      |
|--------------------------------|----------------------|
| EN ISO 14971:2012              | EN ISO 15223-1:2016  |
| EN 1041:2008+A1:2013           | ISO 10993-1:2018     |
| EN ISO 10993-5:2009            | EN ISO 10993-10:2013 |
| EN 14683:2019+AC:2019 Type IIR |                      |

**Signature:** *Wu Pingshen*  
**Name / Position:** Wu Pingshen / GM  
**Date:** 2020/11/29  
**Place:** Taiwan / China



On behalf of SUNGO Europe office, I hereby declare  
EU REP of this company who have the decision

**Sungo**  
SUNGO EUROPE B.V.

Authorized Signature

# CIBG REGISTRATION



CIBG  
Ministerie van Volksgezondheid,  
Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

SUNGO Europe B.V.  
T.a.v. de heer R. Luo  
Olympisch Stadion 24  
1076 DE Amsterdam

Datum: 20 november 2020  
Betreft: notificatie medisch hulpmiddel klasse I

Geachte heer Luo,

Hierbij bevestig ik de ontvangst op 6 november 2020 van de notificatie van het medische hulpmiddel klasse I, dat bedrijf Linghe International co. Ltd., met Europees gemachtigde SUNGO Europe B.V., als fabrikant overeenkomstig Verordening (EU) 2017/745 (MDR) op de markt wenst te gaan brengen. Het product is onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie over dit product het bijbehorende kenmerk te vermelden en het bij telefoongesprekken bij de hand te houden.

**LINGHE Medical Face Mask (Non-Sterile)**  
**(geen merknaam) (NL-CA002-2020-54166)**

Ik wijs u erop dat medische hulpmiddelen die op de markt gebracht worden volgens de MDR over een systeem voor hulpmiddelindicatie (UDI) moeten beschikken<sup>1</sup> en dat fabrikanten, gemachtigden en importeurs in de Europese databank voor Europese hulpmiddelen (Eudamed) moeten worden geregistreerd<sup>2</sup>. Bijlage VI van de MDR bevat de bij de registratie te verstrekken gegevens.

Op dit moment is Eudamed nog niet in gebruik, zodat het wat betreft het bovenstaande voldoende is dat u uw product overeenkomstig de huidige wet- en regelgeving hebt genotificeerd.

Zodra Eudamed volledig in gebruik is, wordt de fabrikant of diens gemachtigde geacht binnen achttien maanden bovenstaand hulpmiddel te registreren in Eudamed.<sup>3</sup>

#### Farmatec

Bezoekadres:  
Hoforen  
Rijnstraat 50  
2515 XP Den Haag  
T 070 340 6161

<http://hulpmiddelen.farmatec.nl>

#### Inlichtingen bij:

T.I. van Langeveld - Baas

medische\_hulpmiddelen@  
minvws.nl

#### Ons kenmerk:

CIBG-20205366

#### Bijlagen

-

#### Uw aanvraag

6 november 2020

*Correspondentie uitsluitend  
richten aan het retouradres met  
vermelding van de datum en het  
kenmerk van deze brief.*

<sup>1</sup> O.g.v. art. 29 MDR.

<sup>2</sup> O.g.v. art. 31 MDR.

<sup>3</sup> [www.gamd-europe.eu/wp-content/uploads/2018/05/FAQ\\_MDR\\_180117\\_VI.0-1.pdf](http://www.gamd-europe.eu/wp-content/uploads/2018/05/FAQ_MDR_180117_VI.0-1.pdf). Zie vraag en antwoord nummer 20.