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 $<5\mu m$.

· 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℃, 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

TEST REPORT TUCHENG

COPY

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

Report No.: TAG9I776 Quantity: 1PC Page Order/Pages: (P1/5) 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
Sub-Micron Particulate Filtration Efficiency(%) (0.1μm PSL)	1	98.68	ASTM F2100-2019 9.3 ASTM F2299-2017 Flow rate:28.1 (Liter/min)
	2	98.72	
	3	98.66	
	4	98.72	
	5	98.71	
	Ave.	98.70	
Air Exchange Pressure (mmH2O/cm²)	1	3.7	ASTM F2100-2019 9.2 EN 14683:2019 Annex C
	2	4.1	
	3	3.7	
	4	4.0	
	5	3.7	
Flammability (as Received)		DNI	ASTM F2100-2019 9.5 CPSC 16 CFR 1610-2008

Note: 1mmH2O=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

TEST REPORT TUCHENG

COPY

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

Report No.: TAG91776 Quantity: 1PC Page Order/Pages: (P2/5) 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
Synthetic Blood Penetration Pressure:80 mmHg	1	None Seen	ASTM F2100-2019 9.4 ASTM F1862-2017
	2	None Seen	
	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

COPY

TEST REPORT TUCHENG

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

Report No.: TAG91776 Quantity: IPC (P3/5) Page Order/Pages: NIL Ref. No.:

Linghe International co. Ltd.(U3353) Mask

Report Title: Item:

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

Test Items		Test Results	Test Methods
Synthetic Blood Penetration Pressure:80 mmHg	17	None Seen	ASTM F2100-2019 9.4 ASTM F1862-2017
	18	None Seen	
	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

TEST REPORT TUCHENG

COPY

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

Report No.: TAG9I776 Quantity: 1PC 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 Efficiency (BFE)(%) Staphylococcus aureus ATCC 6538	1	99.8	ASTM F2100-2019 9.1 ASTM F2101-2019
	2	99.6	
	3	99.6	
	4	99.7	
	5	99.8	

Note: Control average: 2407 CFU.

Note: Mean particle size: 2.9 μm.

Note: Testing side: outside of specimen.

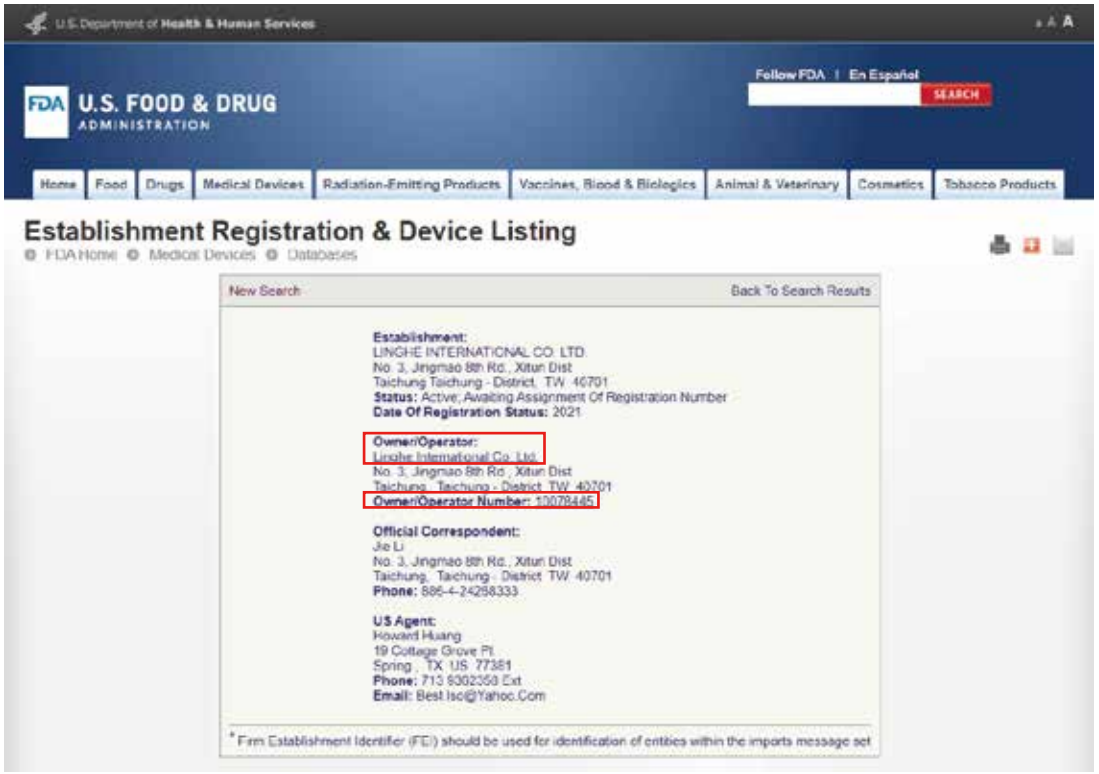
Note: Testing area: 39.5 cm^2.

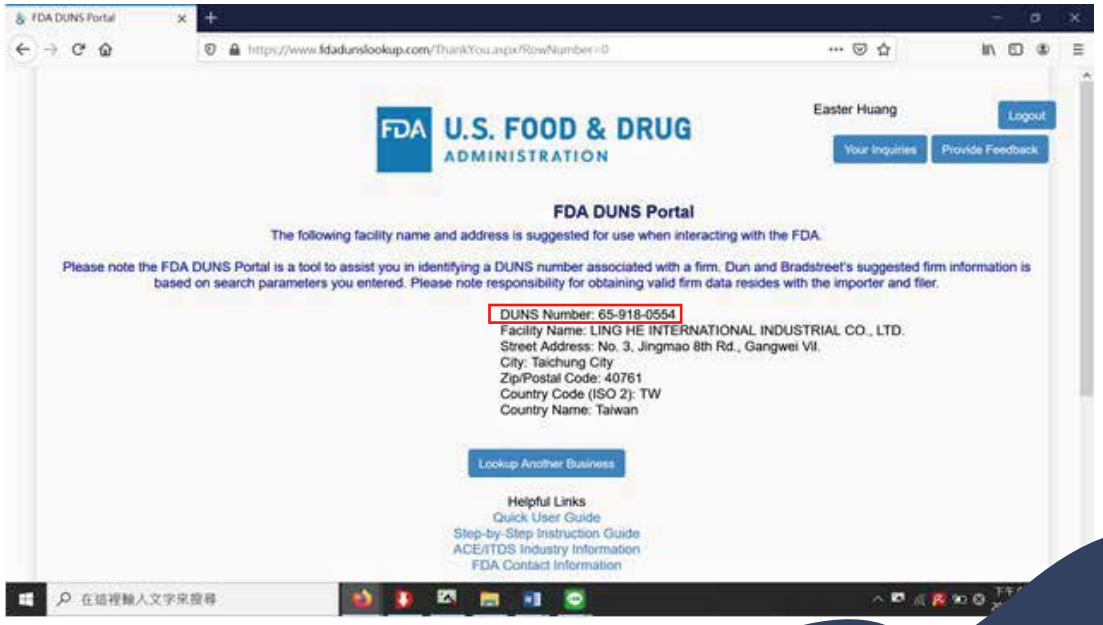
Note: Flow rate : 28.3 L/min.

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



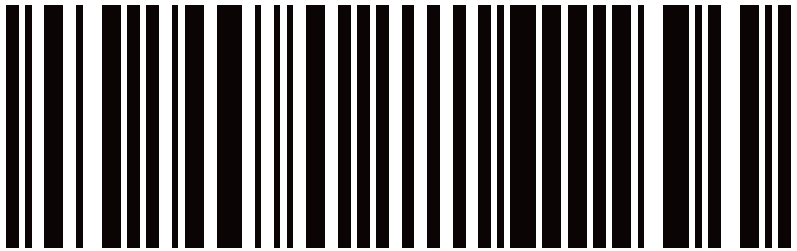


MEDICAL FACE MASK

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

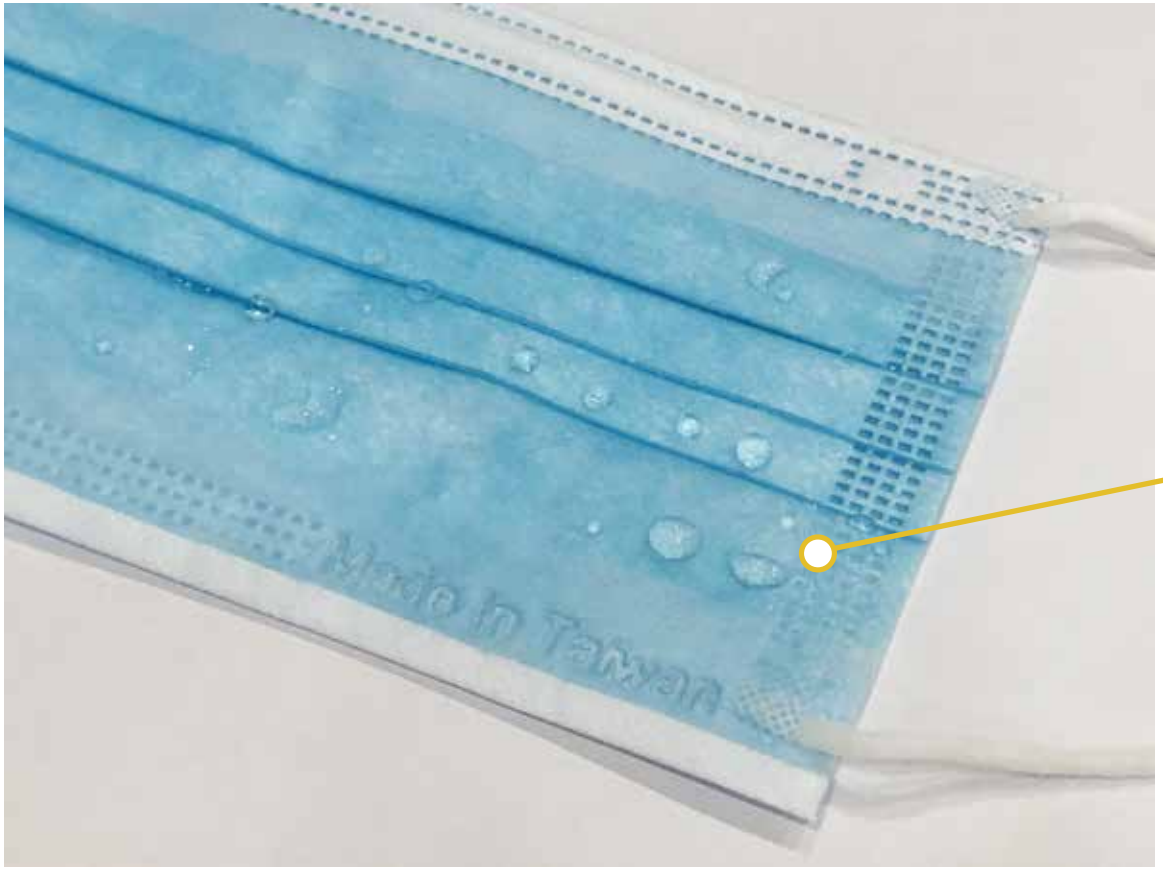
SPECIFICATION/ PACKAGING

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

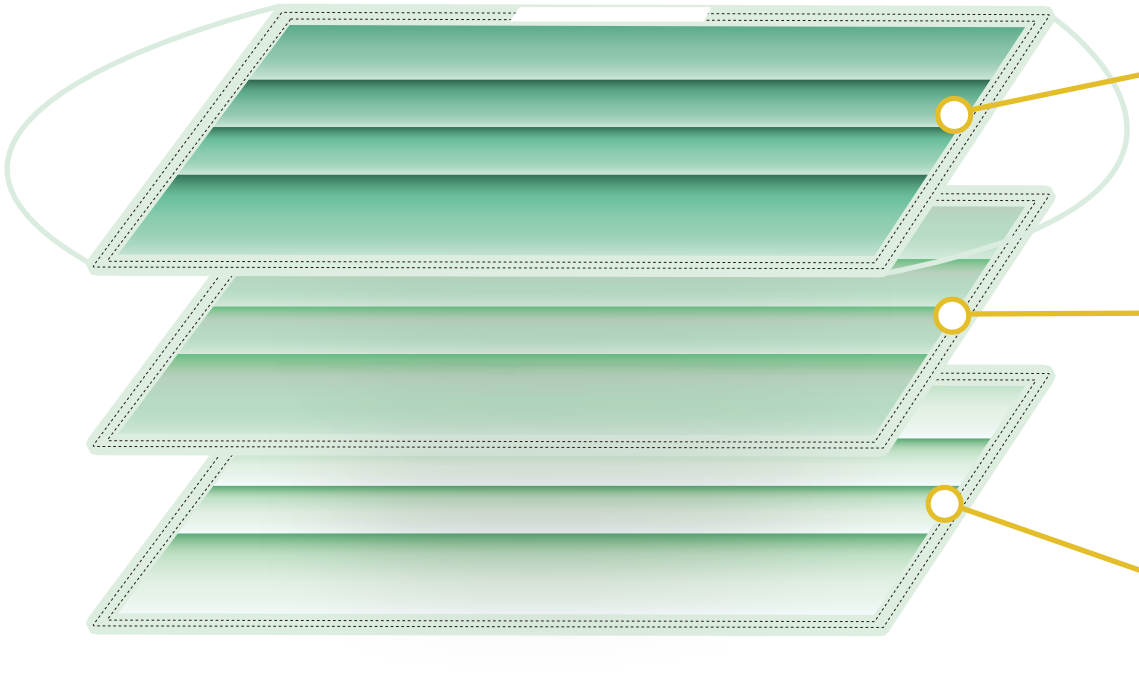


FUNCTION FACE MASK

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



MEDICAL FACE MASK



Outer layer

Water-repellent
non-woven fabric
Polypropylene

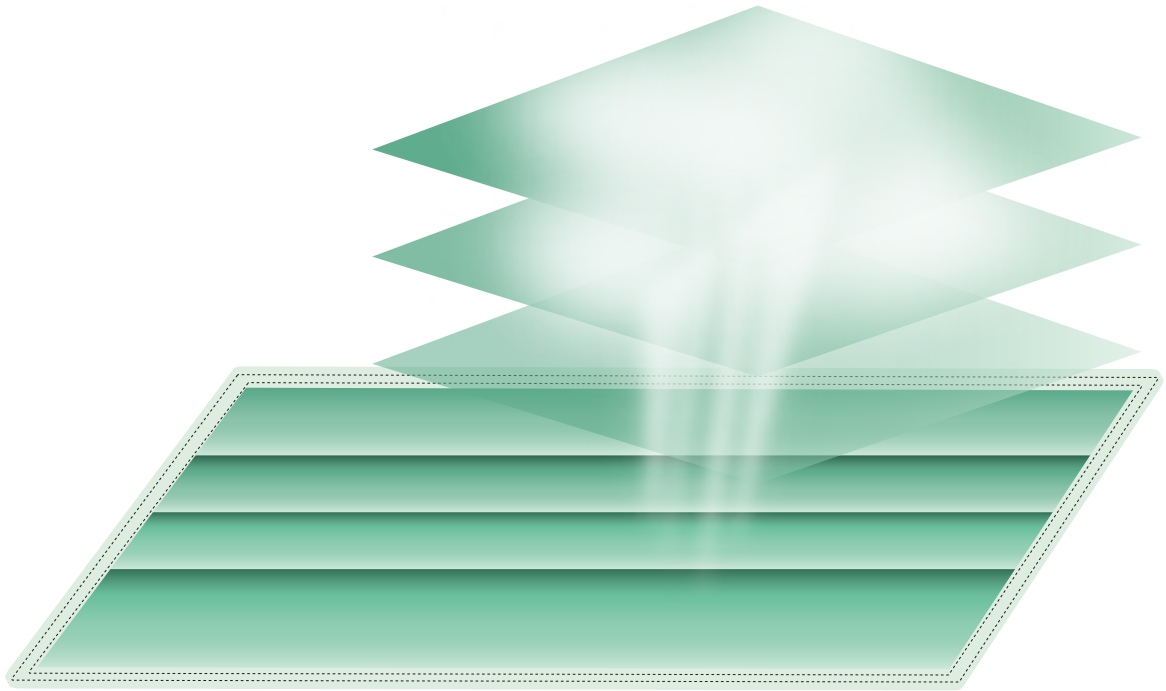
Filter layer

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 compositenon-woven, inhibit the growth of bacteria.

VARIETY

Orange Pink Black

Green Blue

Purple Purple Yellow Orange

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 (mmH2O/cm²)	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 μm.

Note: Testing side: outside of specimen.

Note: Testing area: 39.5 cm².

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 TEST REPORT

土城場區 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 (Pa/cm²)	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

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 TEST REPORT　土城場區 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: (P2/6)　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	1	無穿透	EN 14683:2019
壓力:120 mmHg (16.0 kPa)	2	無穿透	ISO 22609:2004
	3	無穿透	
	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	

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

黃玉婉#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 TEST REPORT　土城場區 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	17	無穿透	EN 14683:2019
壓力:120 mmHg (16.0 kPa)	18	無穿透	ISO 22609:2004
	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

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 TEST REPORT

土城場區 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 (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 TEST REPORT　土城場區 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	

本試驗報告僅供參考，不做任何正式文件證明用

註：對照組的平均菌落數：1835 CFU。

註：平均粒徑：3.2 μm。

註：測試面：外側。

註：測試面積:39.5 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）

TESTING REPORT FACE MASK

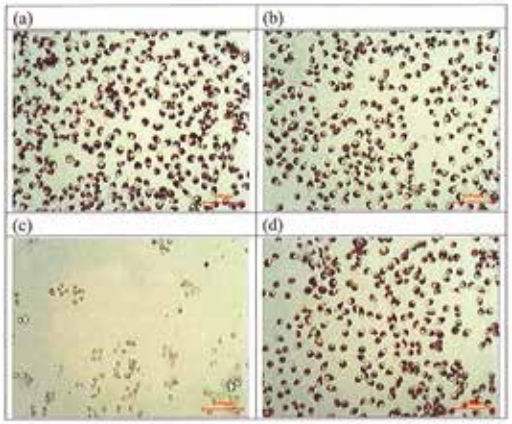


Figure 1. The observed cell morphology of L929 cells after being treated for 24 h under 100X inverted microscope.
a. Blank (B): culture medium
b. Negative control (NC): HDPE
c. Positive control (PC): 10% DMSO
d. Test sample (S): LINGHE MEDICAL FACE MASK (Non-sterile)

Appendix 1. 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

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

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 ($OD_{570\ nm}$)	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

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-Nov/18, lot2-Nov/20, Lot3 Nov/23)each working day produce 60000 Pcs to 100k Pcs (Nov working lots as Nov2/3/4/5/6/7/9/10/11/12/13/14/16/17/18/19/20/21/23/24/25/26/27/30)
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: 2020-12-28

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 14683:2019 and AS4381:2015) with the following exception: ISO 22609 requires testing to be performed in an environment with a temperature of 21 ±5℃ 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 Side Outside
Pre-Conditioning Minimum of 4 hours at 21 ± 5 ℃ and 85±5 % relative humidity (RH)
Test Conditions 22.3 ℃ 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: 160 mmHg (21.3 kPa)

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Ⅰ類：一般及整型外科手術裝置　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

核准展延至	年　月　日	年　月　日	年　月　日	年　月　日
文號				

MK 016749

CERTIFICATION

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：臺中市西屯區經貿八路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

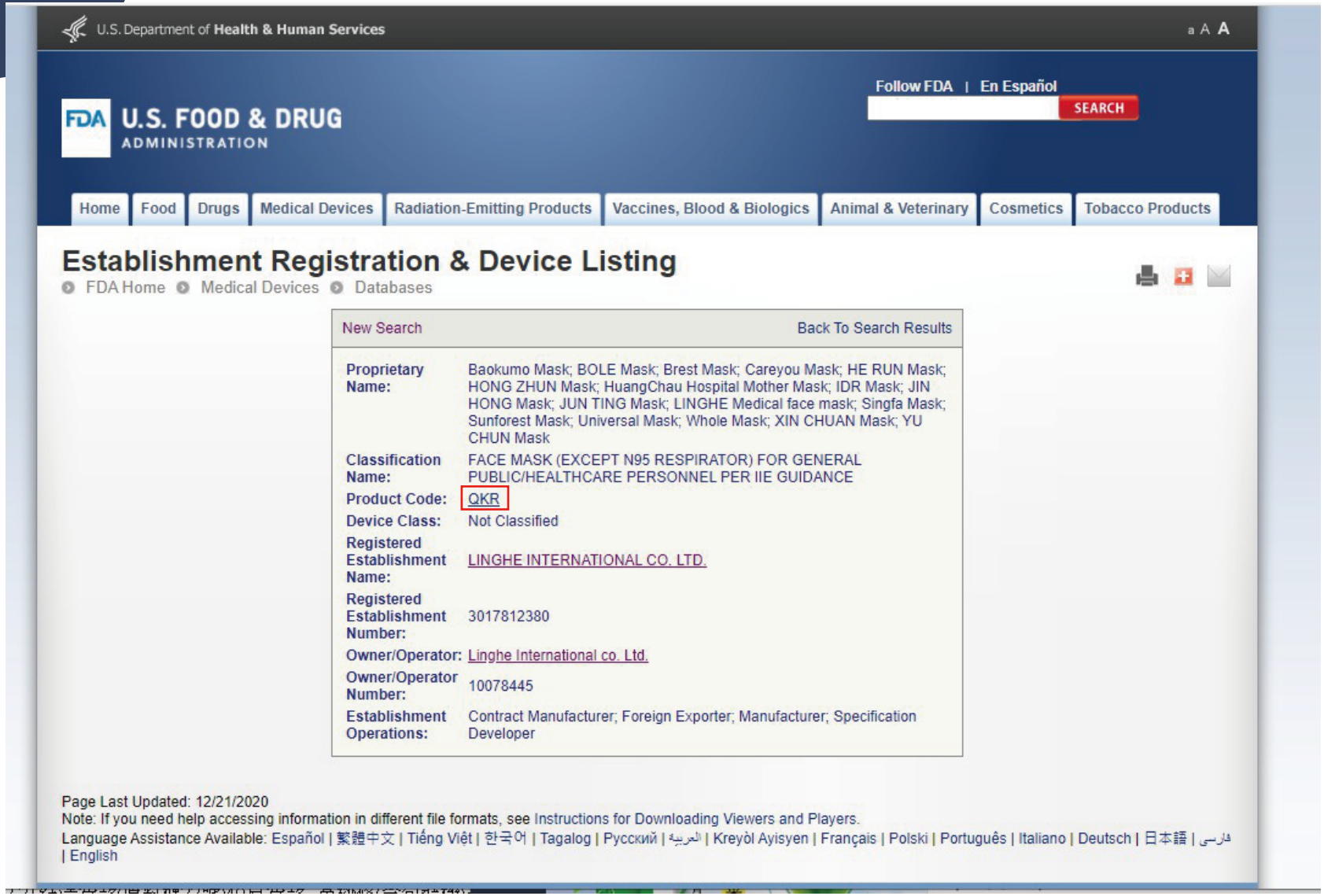
負 責 人：趙麗玲

上開藥商依照藥事法第二十七條之規定發給許可執照

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			主要產品：222 醫療器材及用品(3329 其他醫療器材及用品)。

FDA REGISTRATION



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Establishment Registration & Device Listing

FDA Home > Medical Devices > Databases

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Proprietary Name:	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
Classification Name:	FACE MASK (EXCEPT N95 RESPIRATOR) FOR GENERAL PUBLIC/HEALTHCARE PERSONNEL PER IIE GUIDANCE
Product Code:	QKR
Device Class:	Not Classified
Registered Establishment Name:	LINGHE INTERNATIONAL CO. LTD.
Registered Establishment Number:	3017812380
Owner/Operator:	Linghe International co. Ltd.
Owner/Operator Number:	10078445
Establishment Operations:	Contract Manufacturer; Foreign Exporter; Manufacturer; Specification Developer

Page Last Updated: 12/21/2020

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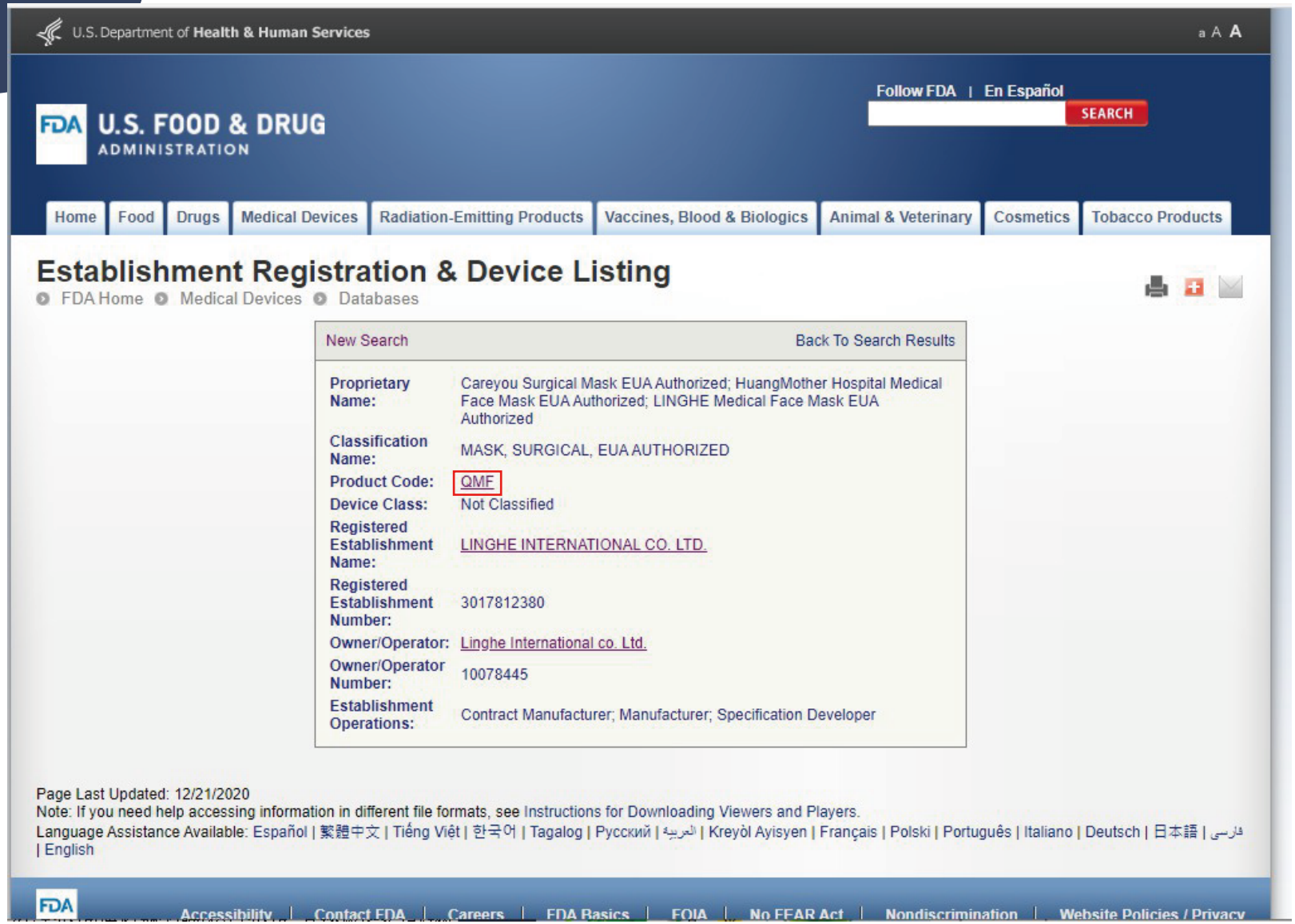

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Proprietary Name:	Careyou Surgical Mask EUA Authorized; HuangMother Hospital Medical Face Mask EUA Authorized; LINGHE Medical Face Mask EUA Authorized
Classification Name:	MASK, SURGICAL, EUA AUTHORIZED
Product Code:	QMF
Device Class:	Not Classified
Registered Establishment Name:	LINGHE INTERNATIONAL CO. LTD.
Registered Establishment Number:	3017812380
Owner/Operator:	Linghe International co. Ltd.
Owner/Operator Number:	10078445
Establishment Operations:	Contract Manufacturer; Manufacturer; Specification Developer

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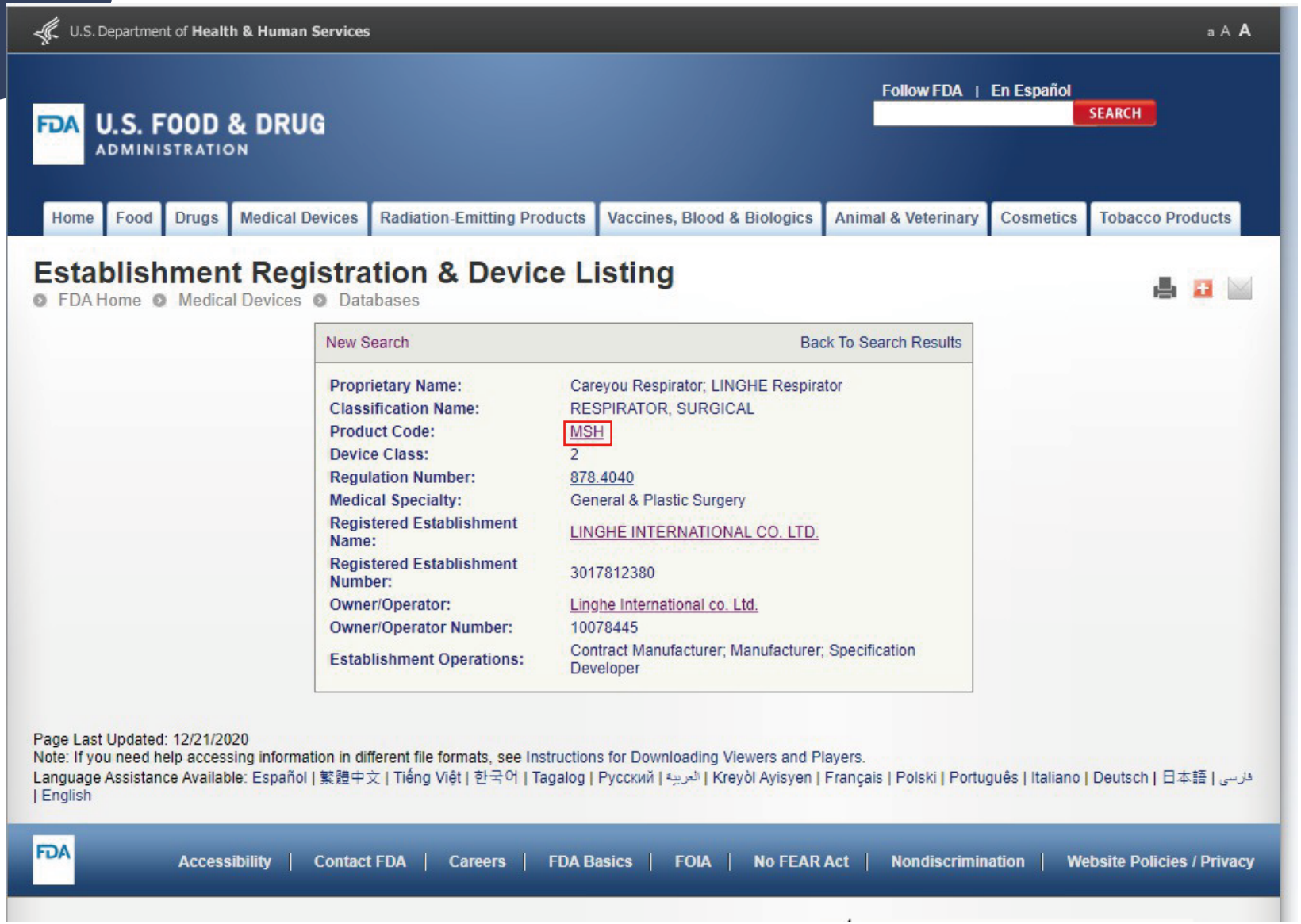
FDA REGISTRATION



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

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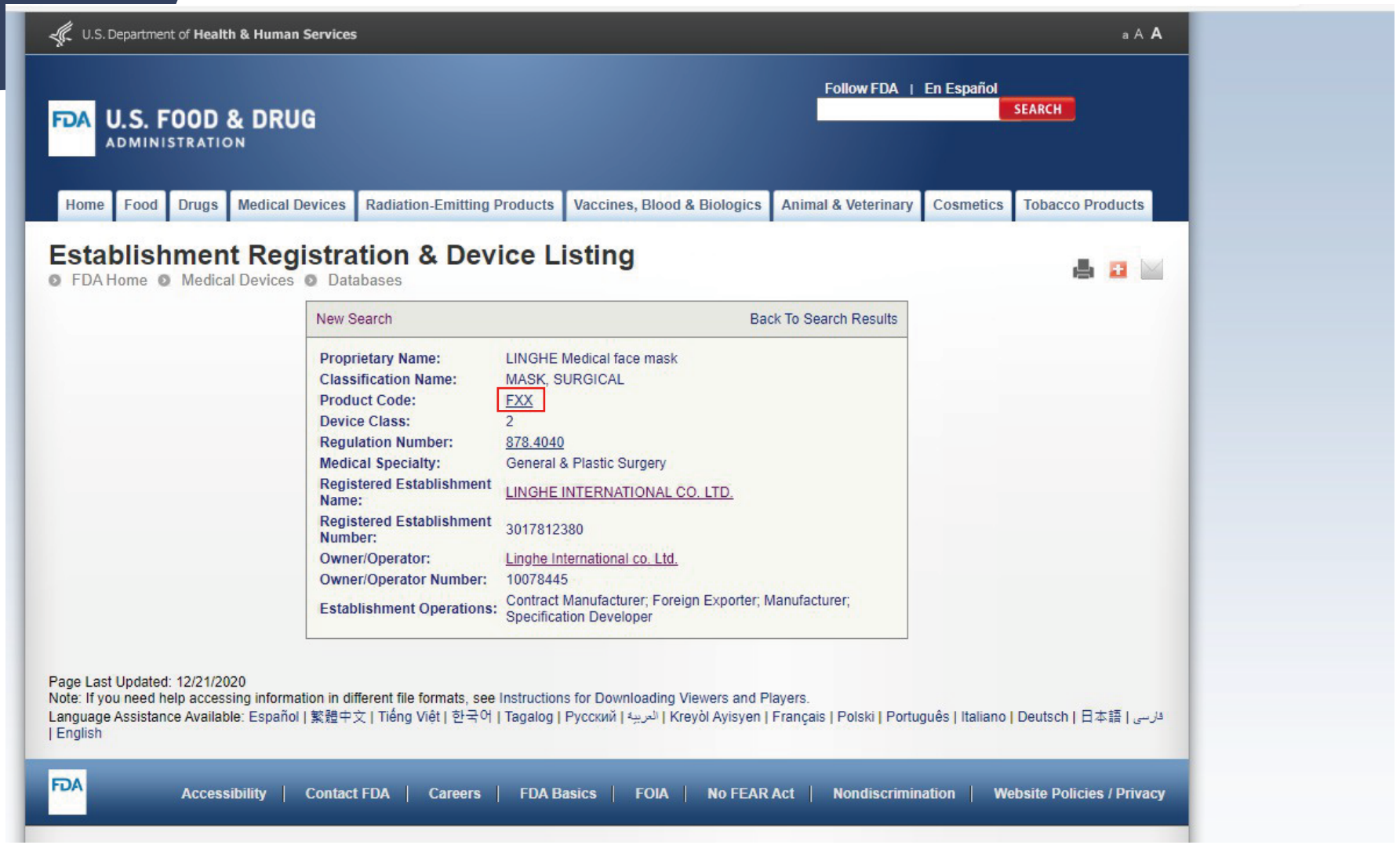
FDA REGISTRATION



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

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CE REGISTRATION

CE

DECLARATION OF CONFORMITY

CE

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 Procedure:	Annex II+III of Regulation (EU) 2017/745
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:

Name / Position: Wu Pengshen / GM

Date: 2020/11/29

Place: Taiwan / China

令和國際實業有限公司

On behalf of SUNGO Europe office, I confirm that we are EU REP of the company who have this document

Sungo

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

Farmatec

Bezoekadres:
Heftoren
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.

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[1] en dat fabrikanten, gemachtigden en importeurs in de Europese databank voor Europese hulpmiddelen (Eudamed) moeten worden geregistreerd[2]. 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.[3]

[1] O.g.v. art. 29 MDR.
[2] O.g.v. art. 31 MDR.
[3] www.camd-europe.eu/wp-content/uploads/2018/05/FAQ_MDR_180117_V1.0-1.pdf. Zie vraag en antwoord nummer 20.