SINO MEDIC

# N95 /N99 medical mask
# Disposable medical masks

- **was established in Tainan, Taiwan in 2008**

- **The company has long been engaged in the professional manufacturing of various medical masks for up to 12 years.**

- **The marketing channels of medical masks in Taiwan: National Taiwan University Hospital, National Cheng Kung University Hospital, Kaohsiung Medical College, Large domestic clinics and franchised pharmacy across the country…etc.**

- **During the anti-epidemic period of the COVID-19 in 2020, our factory was called by the government to become one of the team members of the 『 Taiwan National Mask Production Team 』.**

- **In 2020, the company extended its sales area to the international medical mask market. In the same year, the company obtained CE EU certification and FDA approval by the US FDA.**

# Comparison of features

| features Item | Our N95 (FFP2) | Well know branded N95 |
|---|---|---|
| Filter method | The world's only "nano-microporous filter" filter material that uses physical filtration. | 1. Traditional electrostatic adsorption filter. |
| Pro. | 1. the PFE>99% is maintained for three years due to physical filtration.<br>2. Light and breath freely.<br>3. Washed more than 10 times , it still maintains BFE & PFE > 99 %.<br>4. Not afraid of moisture.<br>5. CE & FDA approval | 1. The company is famous.<br>2. Head loop is comfortable to wear.<br>3. There are foundry factories all over the world.<br>4. CE & FDA(510 K) approval.<br>5. Widely known by doctors. |
| Con. | 1. Insufficient brand awareness internationally.<br>2. 6 million pieces per month<br>3. Niosh testing is accomplished, but waiting for certification | 1. Afraid of moisture.<br>2. From the factory to the delivery and preservation process, if the electrostatic layer station ingon power is insufficient, will lead to a rapid decline in protection efficiency.<br>3. Only use once. |
| Price | 1. Stable price<br>2. High C/P value<br>3. Provide traders with high profits. | 1. Floating price<br>2. High unit price<br>3. There are many fakes in the market |

| | Nano Technology N95 (FFP2)Medical Mask | Nano Technology N99 (FFP3)Medical Mask |
|---|---|---|
| Product number | **CMK-16** | **CMK-161** |
| washable | Can be washed | Can be washed |
| product photo |  |  |
| specification | Mask size:11x15(±0.5CM)<br>Nose piece length: 8(±0.5CM)<br>Ear strap length: 22 (±0.5CM)<br>Mask thickness: 0.62MM | Mask size:11x15(±0.5CM)<br>Nose piece length: 8(±0.5CM)<br>Ear strap length: 22 (±0.5CM)<br>Mask thickness: 0.62MM |
| Quantity (Single Pack) | 500pcs/carton | 500pcs/carton |
| Carton size | 46x53.5x39(CM) | 46x53.5x39(CM) |
| Net weight of outer box | 5.4KG | 5.4KG |
| Gross weight of outer box | 6.5KG | 6.5KG |
| Manufacturing Origin | Taiwan(MIT) | Taiwan(MIT) |
| Shelf life | over 3 years | over 3 years |
| HS CODE | 63079050115 | |
| CE EU certification | ✓ | ✓ |
| FDA approved | ✓ | ✓ |

N95 (FFP2) outward appearance

Internal appearance (With sponge for nose pad)

S hook to enhanced air tightness


Thickness less than 0.62 mm, ultra light and breathable


Actual wearing mask photo

# Are N95 (FFP2) medical masthere any other features of Nono Technology ?

- **Unique nano-filter material: using the most top-quality materials, the high-efficiency filter material with many micro-holes, and the design with three-dimensional air chamber can achieve less burdensome air permeability, and is lighter and thinner than other brands, and breathe better.**

- **Repeatable washing: According to the "Taiwan Textile Research Institute (TTRI) Washing Test Report", after washing more than 10 times, the protection efficiency can still be maintained above PFE 99%, and the protection will not decrease after washing.**

- **More economical and more environmentally friendly :Take advantage of reproducible and washable, while prolonging the life of the mask, and also contribute to environmental protection.**

- **Think about it: how many people in the world throw away a piece of mask a day, and the inner meltblown layer is made of plastic material, which will never be decomposed all year round... The longer the time, the more pollution burden is added to the earth.**

# How to wash and clean the mask?

**Cleaning Procedure:**

1. It can be washed about 10 times.
2. After applying cleaning products with sterilization effects on both the inside and outside of the mask, use a toothbrush to gently clean the surface of the mask, rinse the mask directly under the tap with water on both sides, and then place it directly in a ventilated place to dry.

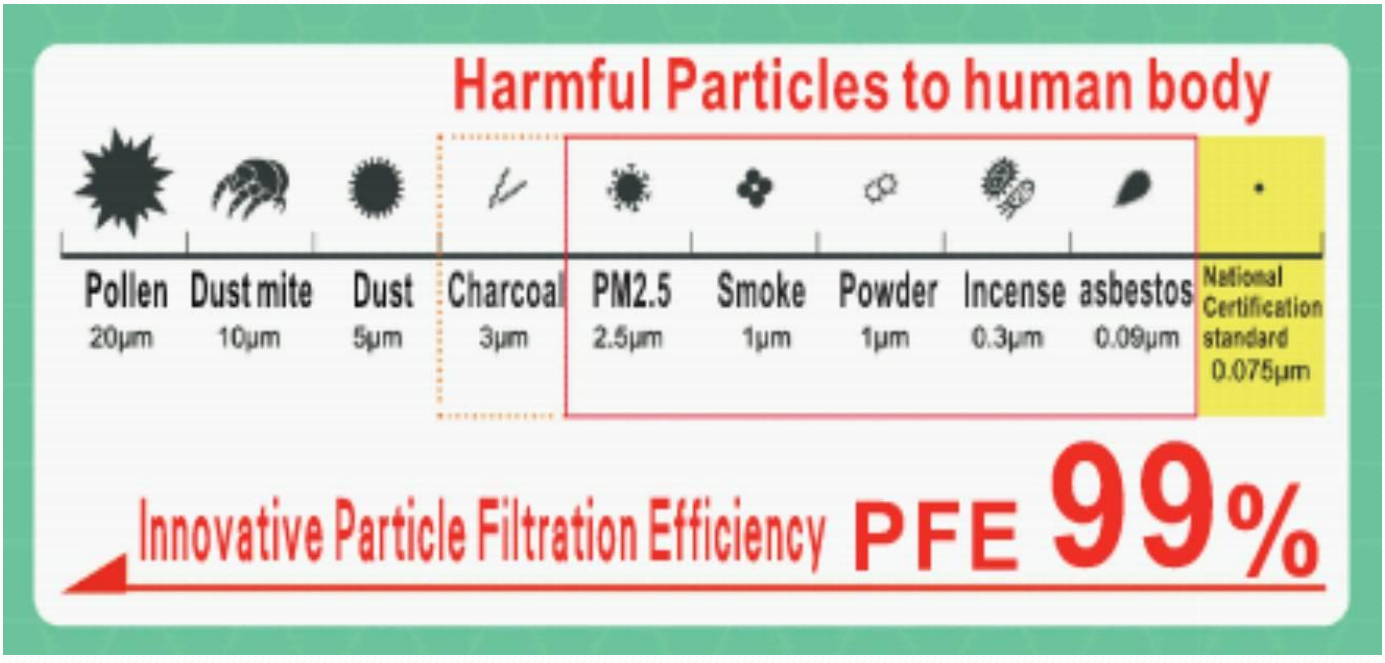
**Caution:**

- Remember not to twist or knead the body of the mask. This action will reduce the arrangement of the inner layer of the nanofilter material and affect the filtration efficiency.
- When you breathe, you smell the mask smelly /stinky or the surface of the mask is dirty / damaged. Please discard the mask immediately and replace it with a new one.

# What is the difference between the NANO technical nano N95 (FFP2) medical mask and the medical masks on the market?

- General plane medical masks protect against particles PM3 that are larger than bacteria, but those harmful to the human body are all particles below PM2.5.

- Nanotechnology N95 (FFP2) medical mask can provide 99% protection against PM0.075 particles, providing more comprehensive protection.



# #1 Q & A for users
# Is the unit price of NANO N95 mask more expensive than the KN95 made in China?

- **NANC N95 (FFP2) mask is the world's only and first new medical mask.**
- **It has stable protection performance under long-term storage, and has the air permeability when worn for a long time**
- **Tested by experiments, medical masks with traditional electrostatic filter media have been stored for more than 3 months, and the filtering power will drop by 20%~30%!**
- **Therefore, I hope that consumers can think seriously: Who wants to buy a mask that has only 80% filtration capacity remaining for 3 months?**
- **Or do you want to buy a medical mask that can maintain a stable 99% protection and more breathable and washable?**
- **A newly released new technology cannot be compared with the price of ordinary technology products on the market. What's more, the safety of life cannot be considered by price?**

# ＃2 Q & A for users
# What are the certifications obtained for NANO N95 (FFP2) masks?

- **The factory has successfully obtained FDA approval with listing number & EUA and CE certification (B & C2).**

- **The International Bureau of Standards ISO9001 and ISO13485 certificates and orthographic marks.**

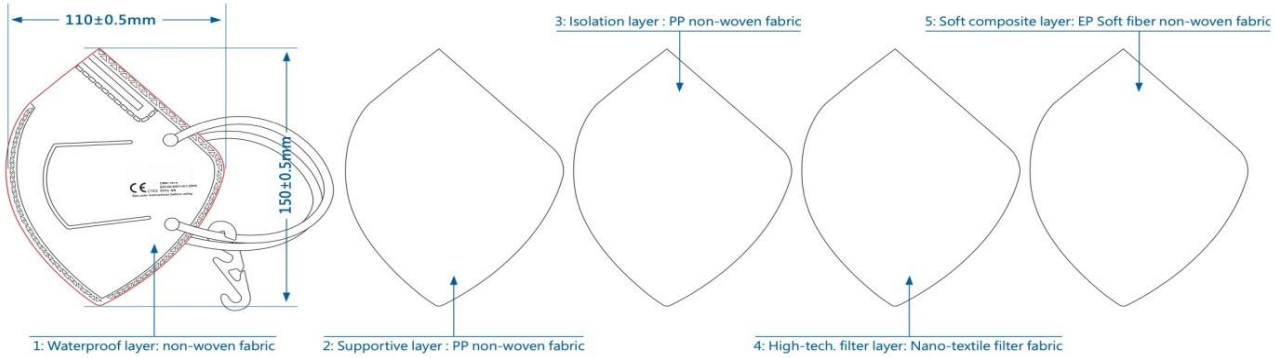
- **Obtained the only medical mask license in Taiwan that can manufacture N99 (FFP3).**

- **MIT smile badge expression [Safe, healthy and trustworthy] [Made in Taiwan, genuine products] A high standard certification mark.**

# layer structure

**The layer structure of Formosa Energy-Carbon FFP2 mask are as follows:**

1. **First layer: Waterproof material**
   **PP water-repellent material is non-woven fabric, which can block the adhesion of pathogenic droplets or blood.**
2. **Second layer: Supportive fabric material**
   **Special non-woven fabric support material can make the mask three-dimensional without deformation.**
3. **Third layer: Isolation fabric material**
   **The PP isolation layer is non-woven fabric and can be blocked.**
4. **Fourth layer: High-tech nano-textile fabric material**
   **High-tech nano-textile fabric filter layer can block bacteria and viruses by 99%.**
5. **Fifth layer: EP Bicomponent fabric material**
   **Soft EP composite fiber non-woven fabric**




A: From outside to inside, the specifications of the cloth are:
1: Waterproof layer: non-woven fabric
2: Supportive layer : PP non-woven fabric
3: Isolation layer : PP non-woven fabric
4: High-tech. filter layer: Nano-textile filter fabric
5: Soft composite layer: EP Soft fiber non-woven fabric

B: Nose bridge: Hot melt adhesive aluminum strip, 80x5

C:Ear strap: Polyester brocade spandex ribbon, 220x4

# Strict quality control

- **Prevent infection between patients and medical staff.**
- **The elasticity of the earhook elastic band is good, and it will not cause ear pain after long wearing**
- **Both raw materials and production are made in Taiwan, and the production environment is carried out in a strictly controlled low-dust room.**
- **It has the characteristics of safety, hygiene, comfort and high protection.**

# Taiwan Ministry of Health and Welfare

# Medical Equipment License

## 衛生福利部第一等級醫療器材許可證

衛部醫器製壹字第 [redacted] 號

中文名稱：N95 醫用口罩(未滅菌)

英文名稱：[redacted]

類　　別：第Ⅰ類：一般及整型外科手術裝置

規　　格：空白

藥商名稱：[redacted]

製造廠名稱：[redacted]

製造廠地址：[redacted]

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　107　年　12　月　12　日

有效日期　112　年　12　月　12　日

| 核准展延至 | 年　月　日 | 年　月　日 | 年　月　日 | 年　月　日 |
|---|---|---|---|---|
| 文號 | | | | |

MK 012260

# Taiwan Ministry of Health and Welfare

# Medical Equipment License

## 衛生福利部第一等級醫療器材許可證

衛部醫器製壹字第 006[redacted]號

中文名稱：[redacted] N99 醫用口罩（未滅菌）

英文名稱：[redacted]

類　　別：第Ⅰ類：一般及整型外科手術裝置　　藥商名稱：[redacted]

規　　格：空白　　製造廠名稱：[redacted]

製造廠地址：[redacted]

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　106　年　07　月　21　日

有效日期　111　年　07　月　21　日

| 核准展延至 | 年　月　日 | 年　月　日 | 年　月　日 | 年　月　日 |
|---|---|---|---|---|
| 文號 | | | | |

MK 009049

台灣精碳
FORMOSA ENERGY-CARBON

# FDA(MSH)

## CERTIFICATE OF FDA REGISTRATION

**2020**

This certifies that:

is registered and has listed the following medical device with the U.S. Food and Drug Administration pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

| | |
|---|---|
| Status: | **Active** |
| Establishment Registration: | |
| Owner/Operator Number: | |
| Proprietary Name: | |
| Device Classification Name: | **RESPIRATOR, SURGICAL** |
| Product Code: | **MSH** |
| Regulation Number: | **878.4040** |
| Listing Number: | |

Compliance Engineering, Inc. makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Compliance Engineering, Inc. assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Compliance Engineering, Inc. is not affiliated with The U.S. Food and Drug Administration.

Kenneth Grant

**US Agent:**
**Compliance Engineering, Inc.**
**USA TEL: 516-984-7287**
**Taiwan TEL: 04-25685848**

**Kenneth Grant**
**Executive Director**
Compliance Engineering, Inc.

# CE EN149 B+C2 certificate(1/8）

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CERTIFICATION

NB 2163

## EU TYPE EXAMINATION CERTIFICATE

**Certificate No: 2163-P**

Respiratory protective devices, filtering half masks to protect against particles manufactured by

are tested and evaluated according to

**EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking**

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

**Product Definition**

**Brand Name:** **Model:** CMK-16

Filtering half mask

**Classification:** FFP2 NR

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on **30/06/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye - İSTANBUL - TURKEY T:+90 216 455 80 80

# CE EN149 B+C2 certificate(2/8）

UNIVERSAL

UNIVERSAL
CERTIFICATION
NB 2163

## CERTIFICATE OF CONFORMANCE

**Certificate No: 2163-**

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Continues to fulfil the requirements of

**EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking**

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

**Product Definition**

| Model | Class | EU Type Examination Certificate | | |
|---|---|---|---|---|
| | | Serial No | Date | Issuing NB No |
| CMK-16 | FFP2 | 216 | 30.06.2020 | 2163 |

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **30/06/2020** and will be valid for one year, until **29/06/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

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# CE EN149 B+C2 certificate(3/8）

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CERTIFICATION

## TECHNICAL ASSESSMENT REPORT

**REPORT DATE / NO:** 30.06.2020 / 21

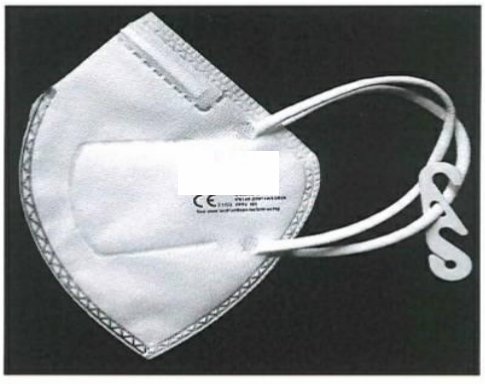
**Manufacturer:**
**Address:** No. 1

This report is for the, given above, manufacturer prepared according to the test results obtained from Jiangsu Quality Supervision and Inspection Center for Special Safety Proteciton Products accredited by CNAS (China National Accreditation Service), signatory to ILAC MRA, with number L-7901 for the product identified below, dated 03.06.2020 with Serial Id STFWT202010821G based on EN 149: 2001 + A1: 2009 standard and the technical file dated 15 June 2020 Version 0 provided by the manufacturer. The sampling of the product is conducted under our supervision for testing from the manufacturing site of the client.

The technical file of the manufacturer, and risk evaluation against the essential health safety requirements and the test report evaluated for their relation with Essential Requirements of Personel Protective Equipment Regulation and found to be appropriate.

This report is an annex and an integral part of the EU Type Examination Certificate issued to the manufacturer. The test results and issued certificate belongs only to the tested model. The technical report consists of a total of 6 pages.

**Product Description:** Particle Filtering Half Mask
**Classification:** FFP2 NR
**Trademark:**



UNIVERSAL CERTIFICATION CE Page 2/6 Notified Body



UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Keyap Ticaret Merkezi, Necip Fazıl Bulvarı, E2 Blok, No:44/84 Y. Dudullu - Ümraniye - İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

# CE EN149 B+C2 certificate(4/8）

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**ESSENTIAL HEALTH and SAFETY REQUIREMENTS GIVEN IN EUROPEAN UNION REGULATION EU 2016/425 CORRESPONDING RISKS FOR THE PRODUCT**

**1.1. Design principles**
**1.1.1. Ergonomics**
PPE must be so designed and manufactured that in the foreseeable conditions of use for which it is intended the user can perform the risk related activity normally whilst enjoying appropriate protection of the highest prossible level. The test resuts with human subjects did not report any problem with the ergonomics of the product.

**1.1.2. Levels and classes of protection**
**1.1.2.1. Highest level of protection possible**
The optimum level of protection to be taken into account in the design is that beyond which the constraints by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or normal performance of the activity.

**1.1.2.2. Classes of protection appropriate to different levels of risk**
Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.

**1.2. Innocuousness of PPE**
**1.2.1. Absence of risks and other inherent nuisance factors**
PPE must be so designed and manufactured as to preclude risks and other nuisance factors under fore seeable conditions of use. The manufacturer declares in his technical file that according to the results of risk analysis and the material properties they use in the manufacturing, the product has no hazardous content for health.

**1.2.1.1. Suitable constituent materials**
The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users. The material selection is processed in the technical manufacturing process and documented.

**1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user**
Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries is evaluated and reported in the test report.

**1.2.1.3. Maximum permessible user impediment**
Any inpediment caused by PPE to movements to be made, postures to be adopted and sensory perception must be minimized; nor must PPE cause movements which endanger the user or other persons.

**1.3 Comfort and effectiveness**
**1.3.1. Adaptation of PPE to user morphology**
PPE must be designed and manufactured in such a way as to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.

**1.3.2. Lightness and design strength**
PPE must be as light as possible without prejudicing design strength and efficiency.
Apart from the specific additional requirements which they must satisfy in order to provide adequate protection against the risks in question (see 3), PPE must be capable of withstanding the effects of ambient phenomena inherent under the foreseeable conditions of use

**1.4. Information supplied by the manufacturer**
The notes that must be drawn up by the former and supplied when PPE is placed on the market must contain all relevant information on:

a) In addition to the name and addressof the manufacturer and/or his authorized representative established in the Community
b) Storage, use, cleaning, maintenance, servicing and disinfection. cleaning, maintenance or disinfectant protection recommended by manufacturers must have no adverse effect on PPE or users when applied in accordance with the relevant instructions;
c) Performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in guestion;
d) Suitable PPE accessories and the characteristics of appropriate spare parts;
e) The classes of protection appropriate to different levels of risk and the corresponding limits of use;
f) The obsolescence deadlineor period of obsolescence of PPEor certain of its components;
g) The type of packaging suitable for transport;
h) The significance of any markings(see 2.12)
i) Where appropriate the references of the Directives applied inaccordance with Article5(6) (b);
j) The name, address and identification number of the notified body involved in the design stage of the PPE

These notes, which must be precise and comprehensible, must be provided at least in the official language(s) of the member state of destination



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# CE EN149 B+C2 certificate(5/8）

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**2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL CLASSES OR TYPES OF PPE**

**2.1. PPE incorporating adjustment systems**

If PPE incorporates adjustment systems, the latter must be designed and manufactured so that, after adjustment, they do not become undone unintentionally in the foreseeable conditions of use.

**2.3. PPE for the face, eyes and respiratory system**

Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised.

The screens for those types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user.

If necessary, such PPE must be treated or provided with means to prevent misting-up.

Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.

**2.4. PPE subject to ageing**

If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging.

If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, his instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.

Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions. The product is for single use and tested with simulated wearing conditioning.

**2.6. PPE for use in potentially explosive atmospheres**

PPE intended for use in potentially explosive atmospheres must be designed and manufactured in such a way that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.

**2.8. PPE for intervention in very dangerous situations**

The instructions supplied by the manufacturer with PPE for intervention in very dangerous situations must include, in particular, data intended for competent, trained persons who are qualified to interpret them and ensure their application by the user.

The instructions must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.

Where PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, the alarm must be designed and placed so that it can be perceived by the user in the foreseeable conditions of use.

**2.9. PPE incorporating components which can be adjusted or removed by the user**

Where PPE incorporates components which can be attached, adjusted or removed by the user for replacement purposes, such components must be designed and manufactured so that they can be easily attached, adjusted and removed without tools.

**2.12. PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety**

The identification or recognition marks directly or indirectly relating to health and safety affixed to these types or classes of must preferably take the form of harmonized pictograms or ideograms and must rem ain perfectly legible throughout the foreseeableuseful life of the PPE. In addition, these marks must be complete, precise and comprehensible so as to prevent any misinterpretation; in particular, where such marks incorporate words or sentences, the latter must appear in the official language(s) of the Member State where the equipment is to be used.

If PPE (or a PPE component) is too small to allow al lor part of the necessary marking to be affixed, the relevant information must be mentioned on the packing and in the manufacturer's notes.

**3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS**

**3.10.1. Respiratory protection**

PPE intended for the protection of the respiratory system must make it possible to supply the user with breathable air when exposed to a polluted atmosphere and/or an atmosphere having an inadequate oxygen concentration.

The breathable air supplied to the user by PPE must be obtained by appropriate means, for example after filtration of the polluted air through PPE or by supply from an external unpolluted source.

The constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure appropriate user respiration and respiratory hygiene for the period of wear concerned under the foreseeable conditions of use.

The leak-tightness of the facepiece and the pressure drop on inspiration and, in the case of the filtering devices, purification capacity must keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user.

The PPE must bear details of the specific characteristics of the equipment which, in conjunction with the instructions, enable a trained and qualified user to employ the PPE correctly.

In the case of filtering equipment, the manufacturer's instructions must also indicate the time limit for the storage of new filters kept in their original packaging.



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# CE EN149 B+C2 certificate(6/8）

UNIVERSAL CERTIFICATION

Technical Assessment of EN 149: 2001 + A1: 2009 Standard and other Standards it refers to, Clauses Corresponding to the (EU) 2016/425 Regulation, Essential Health and Safety Requirements given above.

| Conforming to EN 149:2001 + A1:2009 Standard Requirements | |
|---|---|
| *Article* **5** | **Classification:** Particle Filtering Half Mask<br>The mask subject to evaluation based on the test results and technical file provided by the manufacturer is classified as;<br>Filtering Efficiency and maximum Total Inward Leakage: Classified as FFP2<br>Mask is classified for single shift use, NR |
| *Article* **7.4** | **Packing:** Particle filtering half masks are packaged to protect them from contamination before use and with cardboard boxes to prevent mechanical damage, the masks are in plastic sealed bags in the card box. The packaging design and the product is considered to withstand the foreseeable conditions of use based on the visual inspection results given in the test report. |
| *Article* **7.5** | **Material:** Materials used in particle filtering half masks, according to the simulated wearing treatment and temperature conditioning results; It is understood it withstands handling and wear over the period for which the particle filtering half mask is designed to be used, it suffered mechanical failure of the facepiece or straps, any material from the filter media released by the air flow through the filter has not constitute a hazard or nuisance for the wearer. The manufacturer declares that the materials used in manufacturing of the mask does not have an adverse affect the health and safety of users.<br>Based on the test results, the masks did not collapse when subject to simulated wearing and temarature conditioning. No nuisance situation is reported during the practical performance tests by human subjects. |
| *Article* **7.6** | **Cleaning and Disinfection:** Particle filtering half mask is **not** designed to be as re-usable. No cleaning or disinfection procedure provided by the manufacturer. |
| *Article* **7.7** | **Practical Performance :**<br>The test report indicates that the human subjects did not face any difficulty in performing the excercises while they were weared by the sample masks, in walking test or work simulation tests. The wearers did not report any failure by means of head harness / straps/ earloops comfort, security of fastenings and field of vision. Also no imperfactions reported during total inward tests about the comfort, field of vision and fastening issues. |

| Assessed Elements | Positive | Negative | Requirements in accordance with EN 149:2001 + A1:2009 and Result |
|---|---|---|---|
| 2.Head harness comfort | 2 | 0 | Positive results are obtained from the test subjects<br>**No imperfections** |
| 3.Security of fastenings | 2 | 0 | |
| 5.Field of vision | 2 | 0 | |

**Conditioning :** (A.R.) As Received, original

| | |
|---|---|
| *Article* **7.8** | **Finish of Parts:** The test report states that the particle filtering half masks, which are likely to come into contact with the user, do not have sharp edges and do not contain burrs. |
| *Article* **7.9.1** | **Total Inward Leakage:**<br>The Total Inward Lekage test is conducted by 10 individual in an aerosol chamber with a walking band, and samples are taken during the condcution of the excercises defined in the standard. The samples used in the test are subjected to the conditioning required in the standard as Temperature conditioning and as received. The face dimensions of the subjects are also reported. The measurement details for each subject and for each excersize are available in the test report.<br><br>It was reported that;<br>At least 47 out of 50 exercise measurement results are smaller or equal to 11%,<br>At least 9 of 10 individual's arithmetic mean is smaller or equal to 8%,<br><br>**According to the reported results, the product meets the limits for FFP1 and FFP2 classification.** |
| *Article* **7.9.2** | **Penetration of filter material:** Sodium Chloride Testing |

| Condition | No. of Sample | Sodium Chloride Testing 95 L/min max (%) | Requirements in accordance with EN 149:2001 + A1:2009 | Result |
|---|---|---|---|---|
| (A.R.) | 19≠ | 0.68 | | |
| (A.R.) | 20≠ | 0.69 | | |
| (A.R.) | 21≠ | 0.71 | FFP1 ≤ 20 % | Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the **FFP1, FFP2** classes. |
| (S.W.) | 22≠ | 0.89 | | |
| (S.W.) | 23≠ | 0.94 | FFP2 ≤ 6 % | |
| (S.W.) | 24≠ | 0.91 | | |
| (M.S. T.C.) | 25≠ | 1.02 | FFP3 ≤ 1 % | |
| (M.S. T.C.) | 26≠ | 1.11 | | |
| (M.S. T.C.) | 27≠ | 1.07 | | |

**Conditioning :** (M.S.) Mechanical Strength
(T.C.) Temperature Conditioning
(A.R.) As Received, original
(S.W.) Simulated wearing treatment

95 L/min = 1,6 $dm^3.sn^{-1}$

UFR-383 12.12.2018 Rev.01



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# CE EN149 B+C2 certificate(7/8）

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*Article* 7.9.2

**Penetration of filter material:** : Paraffin Oil Testing

| Condition | No. of Sample | Paraffin Oil Testing 95 L/min max (%) | Requirements in accordance with EN 149:2001 + A1:2009 | Result |
|---|---|---|---|---|
| (A.R.) | 28# | 0.98 | FFP1 ≤ 20 %<br>FFP2 ≤ 6 %<br>FFP3 ≤ 1 % | Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the **FFP1, FFP2** classes. |
| (A.R.) | 29# | 1.05 | | |
| (A.R.) | 30# | 1.03 | | |
| (S.W.) | 31# | 1.25 | | |
| (S.W.) | 32# | 1.19 | | |
| (S.W.) | 33# | 1.21 | | |
| (M.S. T.C.) | 34# | 1.33 | | |
| (M.S. T.C.) | 35# | 1.46 | | |
| (M.S. T.C.) | 36# | 1.39 | | |

**Conditioning :** (M.S.) Mechanical Strength
(T.C.) Temperature Conditioning
(A.R.) As Received, original
(S.W.) Simulated wearing treatment

*Article* 7.10

**Compatibility with skin:** In Practical Performance report, the likelihood of mask materials in contact with the skin causing irritation or other adverse effect on health was not reported. (No negative reporting on practical performance and TIL test results)

*Article* 7.11

**Flammability :**

| Condition | No. of Sample | Visual inspection | Requirements in accordance with EN 149:2001 + A1:2009 | Result |
|---|---|---|---|---|
| (A.R.) | 37# | Didn't burn | Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame | **Passed** Laboratory claims that the tested items did not burn for 5 seconds and fulfils the requirement of the standard |
| (A.R.) | 38# | Didn't burn | | |
| (T.C.) | 39# | Didn't burn | | |
| (T.C.) | 40# | Didn't burn | | |

**Conditioning :** (A.R.) As Received, original
(T.C.) Temperature Conditioning

*Article* 7.12

**Carbon dioxide content of the inhalation air:**

| Condition | No. of Sample | $CO_2$ content of the inhalation air [%] by volume | An average $CO_2$ content of the inhalation air | Requirements in accordance with EN 149:2001 + A1:2009 | Result |
|---|---|---|---|---|---|
| (A.R.) | 41# | 0.55 | 0.56 [%] | $CO_2$ content of the inhalation air shall not exceed an average of 1,0% by volume | **Passed** Filtering half masks fulfil requirements of the standard |
| (A.R.) | 42# | 0.57 | | | |
| (A.R.) | 43# | 0.56 | | | |

**Conditioning :** (A.R.) As Received, original

*Article* 7.13

**Head harness:** In Practical Performance and TIL test reports no adverse effects have been reported for donning and remove of the mask also the results of these tests indicates that the head harness are capable of holding the mask firmly enough.

*Article* 7.14

**Field of vision:** In Practical Performance report, no adverse effects were reported for the field of vision availability when the mask is weared.

*Article* 7.15

**Exhalation Valve(s):** The model under inspection have no valves.

*Article* 7.16

**Breathing Resistance:** Inhalation

The overall evaluation of the results gathered for 9 different samples 3 as received, 3 with temparature conditioning, 3 simulated wearing treatment complies with the limits given in the standard for FFP1, FFP2 and FFP3 classes. This is valid for inhalation results for 30 L/min, 95 L/min and exhalation at 160 L/min. The measurement details for each single mask tested are available in the test report.

**Passed.**





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# CE EN149 B+C2 certificate(8/8）

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| | |
|---|---|
| *Article* 7.17 | **Clogging:** This test is not applied to Particle Filtering Half Mask which is not reusable. *(For single shift use devices, the clogging test is optional test. For re-usable devices test is mandatory.)* |
| *Article* 7.18 | **Demountable Parts:** There are no demountable parts of the mask. |
| *Article* 8 | **Testing:** All tests conducted according to Clause 8 of this standard is available in the test report and are evaluated in this report for qualification and classification of the mask. |
| *Article* 9 | **Marking – Packaging:** Necessary markings are available on the product package (box). The manufacturer and its trademark is clearly visible. The type of the mask and the classification including the status of re-usability, the reference to EN 149:2001+A1:2009 standard, the end date of shelf life, uisng and storage instructions and pictograms and CE mark are available on the product package. The above evaluation is based on the technical document for packaging and marking, for box design. Verified on the Annex 5 of the technical file.<br><br>The technical documentation for mask design (drawing) also evaluated for marking requirements, drawing CMK-1619. The mask template (drawing) indicates that the mask will carry information about the manufacturer / trademark (Formosa Energy-Carbon) of the manufacturer, Type of mask, the reference to EN 149+A1:2009 standard and classification including the re-usability of the mask. The manufacturer also printed CE mark with our Notified Body number. The mask do not have sub-assemblies. Even the tested sample by the laboratory do not carry necessary marking information as stated in the technical documentation, the manufacturer shall follow marking instructions for serial production. Model drawing CMK-1619 exists in the technical file of the manufacturer, Annex 4 of technical file. |
| *Article* 10 | **Information to be supplied by the manufacturer:** In each of the smallest commercially available packaging of the product, implementation (installation instructions) pre-use controls, warning and usage limitations, storage and meanings of symbols / pictograms are defined. User instruction document in the technical file found to be appropriate. The manufacturer shall include this documented user information text in every smallest commertially available package, Annex 2 of Technical file. |

| PREPARED BY | APPROVED BY |
|---|---|
| **Neslihan EKE BİRTÜRK**<br>PPE Expert | **Suat KAÇMAZ**<br>General Manager |

UNIVERSAL CERTIFICATION CE 2163 Notified Body



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# ISO9001 & ISO13485 Certificate

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/IMQ as an IQNet Partner hereby states that the organization

for the following scope:

**Design and manufacture of disposable respirators**

Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

has implemented and maintains a

**Quality Management System**

which fulfills the requirements of the following standard

**ISO 9001:2015**

Issued on: 2017 – 08 – 03

First issued on: 2017 – 08 – 03

for the validity date, please refer to the original certificate* issued by IMQ

Registration Number: IT – 112095

Alex Stoichitoiu
President of IQNET

Ing. Claudio Provetti
President of CISQ

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THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/IMQ as an IQNet Partner hereby states that the organization

for the following scope:

**Design and manufacture of disposable respirators**

Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

has implemented and maintains a

**Quality Management System**

which fulfills the requirements of the following standard

**ISO 13485:2016**

Issued on: 2017 – 08 – 03

First issued on: 2017 – 08 – 03

for the validity date, please refer to the original certificate* issued by IMQ

Registration Number: IT – 112127

Alex Stoichitoiu
President of IQNET

Ing. Claudio Provetti
President of CISQ

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# 「0.075μm filtration rate」Test Report

劉建新 (06-243-6135)

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

TEST REPORT TUCHENG

Date: May.07,2020 Date of Receipt: Apr.30,2020

Report No.: TFF9D786 Quantity: 1PC Page Order/Pages: (P1/3) Ref. No.: NIL

Report Title: Item: Mask

Address:

| Test Items | | Test Results | Test Methods |
|---|---|---|---|
| Protection Efficiency of Mask(%) (0.075μm NaCl,CMD) | 1 | 98.72 | CNS 14755 Z2125-2011 Flow rate:85.1 (L/min) |
| | 2 | 99.62 | |
| | 3 | 98.87 | |
| | 4 | 98.95 | |
| | 5 | 98.69 | |
| | 6 | 98.88 | |
| | 7 | 99.47 | |
| | 8 | 99.04 | |
| | 9 | 99.27 | |
| | 10 | 99.05 | |
| | Ave. | 99.06 | |



**Test Results 98.69%~ 99.62%**

Note: Sample description was given by the client: TWEC N95 Respirator LOT: 20200428

Note: As the remaining sample was asked to return along with the test report, re-testing would not be possible.

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.

**Protection Efficiency of Mask(%)**

Note: 1.This report is only responsible for the submitted sample(s), which will be kept for one month period.
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3.The test report should not be used for public advertisement and commercial promotion.

Authorized by president of Taiwan Textile Research Institute

Jui-hung Kao
Director, Department of Testing and Certification

Department of Testing and Certification, Taiwan Textile Research Institute
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# 「Respiratory Impedance」 Test Report

劉建新 (06-243-6135)

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

TEST REPORT TUCHENG

Date: May.07,2020 Date of Receipt: Apr.30,2020

Report No.: TFF9D786 Quantity: 1PC Page Order/Pages: (P2/3) Ref. No.: NIL

Report Title: Item: Mask

Address:

| Test Items | | Test Results | Test Methods |
|---|---|---|---|
| Inhalation Resistance (Pa) | 1 | 101.92 | CNS 14755 Z2125-2011 Flow rate:85.1 (L/min) |
| | 2 | 97.02 | |
| | 3 | 89.18 | |
| | 4 | 95.06 | |
| | 5 | 93.10 | |
| | 6 | 101.92 | |
| | 7 | 104.86 | |
| | 8 | 99.96 | |
| | 9 | 102.90 | |
| | 10 | 92.12 | |
| | Ave. | 97.80 | |
| Exhalation Resistance (Pa) | 1 | 100.94 | |
| | 2 | 85.26 | |
| | 3 | 85.26 | |
| | 4 | 87.22 | |
| | 5 | 79.38 | |
| | 6 | 84.28 | |
| | 7 | 97.02 | |
| | 8 | 91.14 | |
| | 9 | 92.12 | |
| | 10 | 86.24 | |
| | Ave | 88.89 | |

This test report is for reference only and should not be used as a formal document.

**Inhalation Resistance**

**Exhalation Resistance**

**Test Results: Higher than standard value**

Note: 1mmH2O=9.8Pa.

Note: Sample description was given by the client: TWEC N95 Respirator

LOT: 20200428

Note: As the remaining sample was asked to return along with the test report, re-testing would not be possible.

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.

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# 「 BFE 」 bacterial filtration rate



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試驗報告 TEST REPORT

日期 Date: May.22,2017 收件日期 Date of Receipt: May.01,2017 土城場區 TUCHENG

報告編號 Report No.: TFF6E003-D 數量 Quantity: 1PC 報告頁次／頁數 Page Order/Pages: (P1/1) 來文字號 Ref. No.: NIL

報告抬頭 Report Title:

試件類別 Item: MASK

地址 Address NO.

| Test Items | | Test Results | Test Methods |
|---|---|---|---|
| Bacterial Filtration Efficiency (BFE)(%) Staphylococcus aureus ATCC 6538 | 1 | > 99.9 | CNS 14774 T5017-2011 9.2 CNS 14775 T4037-2003 |
| | 2 | > 99.9 | |
| | 3 | > 99.9 | |
| | 4 | > 99.9 | |
| | 5 | > 99.9 | |

**Test Results: 99.9%**

Note: Control average: 2016 CFU.

Note: Mean particle size: 3.0 $\mu$m.

Note: Testing side: inside of specimen.

Note: Testing area: 39.5 cm².

Note: As requested by the client, test location: A flat area of mask.

Note: Sample description is given by the client: FORMOSA ENERGY-CARBON N95 RESPIRATOR

Note: As the remaining sample was asked to return along with the test report, re-testing would not be possible.

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.

**Bacterial Filtration Efficiency(BFE)**

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所長權核發人: Gwo-Tsan Jou
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# 「Synthetic Blood Penetration」

# Test Report

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

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試驗報告 TEST REPORT

日期 Date: May.22.2017 收件日期 Date of Receipt: May.01.2017 土城場區 TUCHENG

報告編號 Report No.: TFF6E003-C 數量 Quantity: 1PC 報告頁次／頁數 Page Order/Pages: (P1/1) 來文字號 Ref. No.: NIL

報告抬頭 Report Title: 試件類別 Item: MASK

地址 Address:

| Test Items | | Test Results | Test Methods |
|---|---|---|---|
| Synthetic Blood Penetration | 1 | none | CNS 14774 T5017-2011 9.5 |
| Pressure: 80 mmHg | 2 | none | CNS 14776 T4038-2003 |
| | 3 | none | |
| | 4 | none | |
| | 5 | none | |
| | 6 | none | |
| | 7 | none | |
| | 8 | none | |
| | 9 | none | |
| | 10 | none | |

Note: Sample description is given by the client: FORMOSA ENERGY-CARBON N95 RESPIRATOR

Note: As the remaining sample was asked to return along with the test report, [illegible] possible.

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.

**Test Results: Sputtering pressure through blood 120**

**Synthetic Blood Penetration Pressure**

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Authorized by president of Department of Testing and Certification
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# 「Flammability」Test Report

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

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試驗報告 TEST REPORT

日期 Date: May.16,2017 收件日期 Date of Receipt: May.01,2017 土城場區 TUCHENG

報告編號 Report No.: TFF6E003-B 數量 Quantity: 1PC 報告頁次／頁數 Page Order/Pages: (P1/1) 來文字號 Ref. No.: NIL

報告抬頭 Report Title: 試件類別 Item: MASK

地址 Address:

| Test Items | | Test Results | Test Methods |
|---|---|---|---|
| Flammability (as Received) | Length wise | DNI | CNS 14774 T5017-2011 9.6 |
| | Width wise | DNI | CNS 10285 L3196-1995 |
| | Rating | Grade 1 | Method C |

Note: "DNI" : Did not Ignite.

Note: Sample description is given by the client: FORMOSA ENERGY-CARBON N95 MASK

Note: As the remaining sample was asked to return along with the test report, re-testing would not be possible.

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.

**Flammability**

**Test Results: Flammability Level 1**

T.T.R.I

Director. Department of Testing and Certification

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# 「Repeat 10 Washes」Test Report

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

試驗報告 TEST REPORT

日期 Date: 2018.12.26　收件日期 Date of Receipt: 2018.10.05　土城場區 TUCHENG　正本 ORIGINAL

報告編號 Report No.: TFF7J109　數量 Quantity: 1件　報告頁次／頁數 Page Order/Pages: (P1/2)　來文字號 Ref. No.: 空白

報告抬頭 Report Title:　試件類別 Item: 口罩

地址 Address:

| 試驗項目 | | 試驗結果 | 試驗方法 |
|---|---|---|---|
| 防護效率(%) (0.075μm NaCl,CMD) | 1 | 99.01 | CNS 14755 Z2125-2011 流速：85.2(Liter/min) |
| | 2 | 99.24 | |
| | 3 | 99.94 | |
| | 4 | 99.77 | |
| | 5 | 99.76 | |
| | 6 | 99.79 | |
| | 7 | 99.75 | |
| | 8 | 99.85 | |
| | 9 | 99.56 | |
| | 10 | 99.47 | |
| | 平均 | 99.61 | |

**Test Results: 99.01%~ 99.94%**

註：水洗方法：CNS 13752 L3243-1996 A法 篩乾x10

註：依委託者所提供來樣資料為：台灣精碳N95醫用口罩

註：試驗報告僅就委託者之委託事項提供試驗結果，不對產品合法性做判斷。

**Submicron particles 0.075 μm Filtration rate**

附記：1.本報告僅對樣品負責，樣品保留期限為一個月。

財團法人紡織產業綜合研究所

檢測及驗證部 主任 周國村

# 「Repeat 10 Washes」Test Report

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

日期 Date: 2018.12.26　收件日期 Date of Receipt: 2018.10.05　試驗報告 TEST REPORT　土城場區 TUCHENG　正本 ORIGINAL

報告編號 Report No.: TFF7J109　數量 Quantity: 1件　報告頁次／頁數 Page Order/Pages: (P2/2)　來文字號 Ref. No.: 空白

報告抬頭 Report Title:　試件類別 Item: 口罩

地址 Address:

| 試驗項目 | | 試驗結果 | 試驗方法 |
|---|---|---|---|
| 吸氣阻抗(Pa) | 1 | 149.94 | CNS 14755 Z2125-2011 流速：85.2(Liter/min) |
| | 2 | 139.16 | |
| | 3 | 154.84 | |
| | 4 | 134.26 | |
| | 5 | 133.28 | |
| | 6 | 149.94 | |
| | 7 | 122.50 | |
| | 8 | 131.32 | |
| | 9 | 137.20 | |
| | 10 | 130.34 | |
| | 平均 | 138.28 | |
| 呼氣阻抗(Pa) | 1 | 152.88 | |
| | 2 | 148.96 | |
| | 3 | 175.42 | |
| | 4 | 149.94 | |
| | 5 | 144.06 | |
| | 6 | 168.56 | |
| | 7 | 121.52 | |
| | 8 | 147.00 | |
| | 9 | 130.34 | |
| | 10 | 151.90 | |
| | 平均 | 149.06 | |

**Inhalation Resistance**

**Exhalation Resistance**

**Test Results: Higher than standard value**

註：水洗方法：CNS 13752 L3243-1996 A法 篩乾x10

註：1mmH2O=9.8Pa。

註：依委託者所提供來樣資料為：台灣精碳N95醫用口罩

註：試驗報告僅就委託者之委託事項提供試驗結果，不對產品合法性做判斷。

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Note: This report is only responsible for ti sample(s), which will be kept for one mont
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# Front view of the Package (Chinese)


190mm

145cm

145mm

# Back view of the Package (Chinese)


190mm

145mm

# Front view of package (US regulations)


190mm

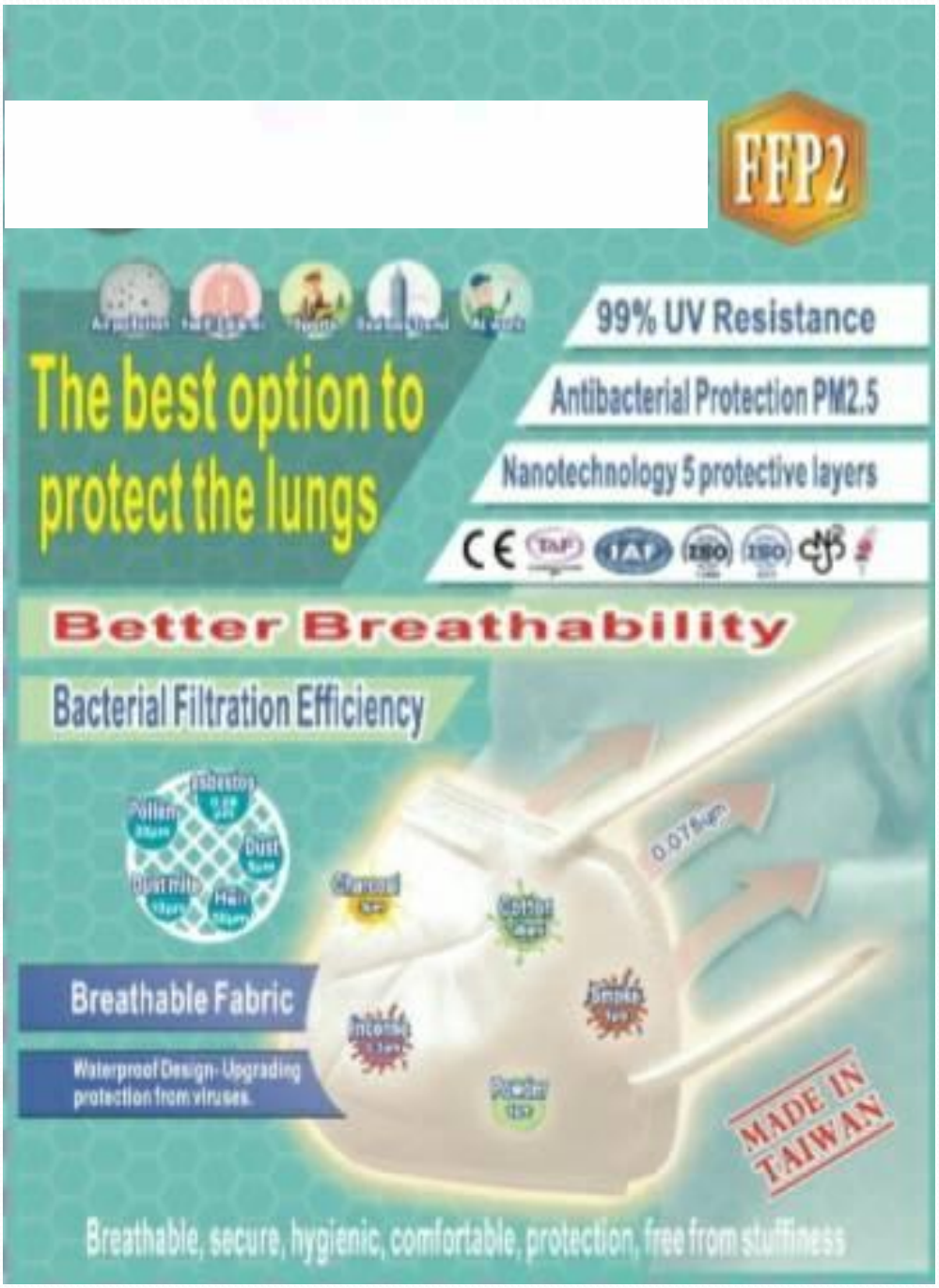
145mm

# Front view of package (US regulations)


190mm

145mm

# Front view of packaging (European regulations)




190mm

145mm

# Schematic diagram of the back of the package (European regulations)


190mm

145mm