
Star Care

Star Care

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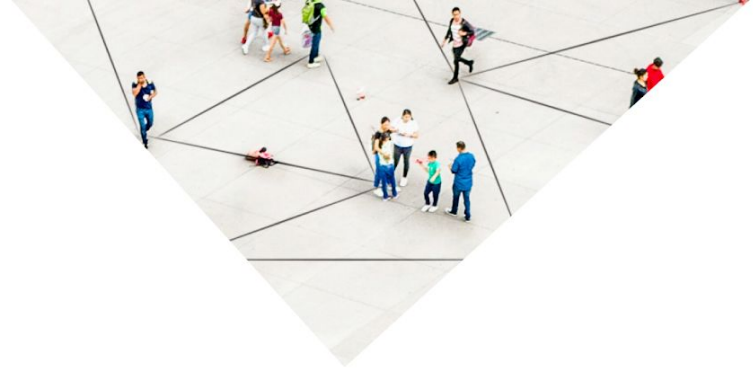

# We are
# Star Care

**Star Care is the care and prevention product line of European holding company Star TIC Innovación.**

Star Care products meet all the official standards and are tried and tested by European certification companies against other products coming directly from Asian companies under false certification and without any control whatsoever.

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# A secure and reliable **manufacturer**

## How do we work?

### Control and safety across the whole chain of production:

1. Supplier qualification
2. Inspection during production (IPQC)
3. Inspection of final product (OQC)
4. Traceability control
5. External audit
6. Additional reliability tests

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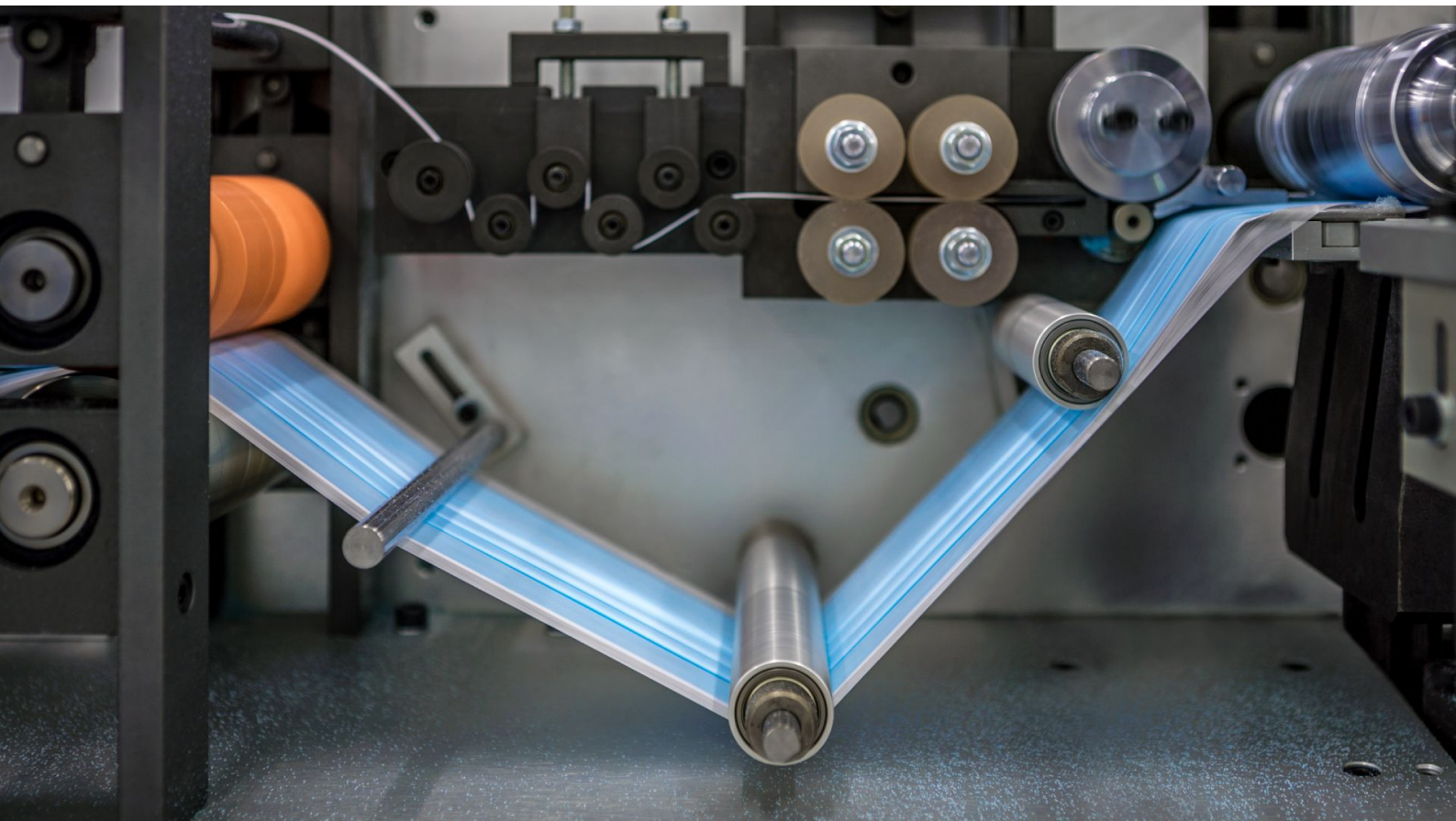
# 1. Supplier qualification

All suppliers involved in the manufacture of our products must meet **strict quality requirements**.

## Our selection process:

1. **Provisional selection** based on strategic criteria and **initial contact**.
2. **Audit:** on-site inspection of the facilities and their technical, process and quality management knowledge.
3. **Background research:** analysis of their financial position to ensure their solvency and the security of potential agreements between the two.
4. **Registration and scoring:** Registration of all information in our database for selection as a supplier for the projects where they constitute the best match.



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# 2. Inspection during production (IPQC)

During manufacturing, we carry out intensive inspections to ensure that **the established minimum objectives are met.** These tests are **independent and in addition to** the ones carried out by the supplier itself, and they are also adapted to the product type. They primarily include:

- **Filtration test**
- **Breathability test**
- **Hygienic controls in production**
- **Suitable clothing, equipment and training for operators**
- **Precision in loading material into the process**

One of the best examples of **rigorousness in quality control is the meltblown fabric**, which is the main material of the mask. We perform preventive checks to detect any changes in origin, fabric or filtration at the entry point of material into the machinery and in the product.


# 3. Inspection of final product (OQC)

We apply **the AQL (Acceptable Quality Limit) standard** and run a set of tests on part of the production selected at random.

## Acceptability levels

Our **acceptability levels are the strictest in the industry.**
Our maximum is 0.65 for *major* defects, 1.5 for *minor* ones and we do not accept any *critical* defects.

## Sample

In the quality controls of our models, the sample size is determined by **Inspection Level III, the most demanding level in existence**. As the table demonstrates, it establishes the largest sample that can be obtained, in order to ensure the highest accuracy.

## Records and control

We record the result of every batch for further analysis and traceability. This follow-up allows us to develop and execute continuous improvement plans and to monitor supplier quality.

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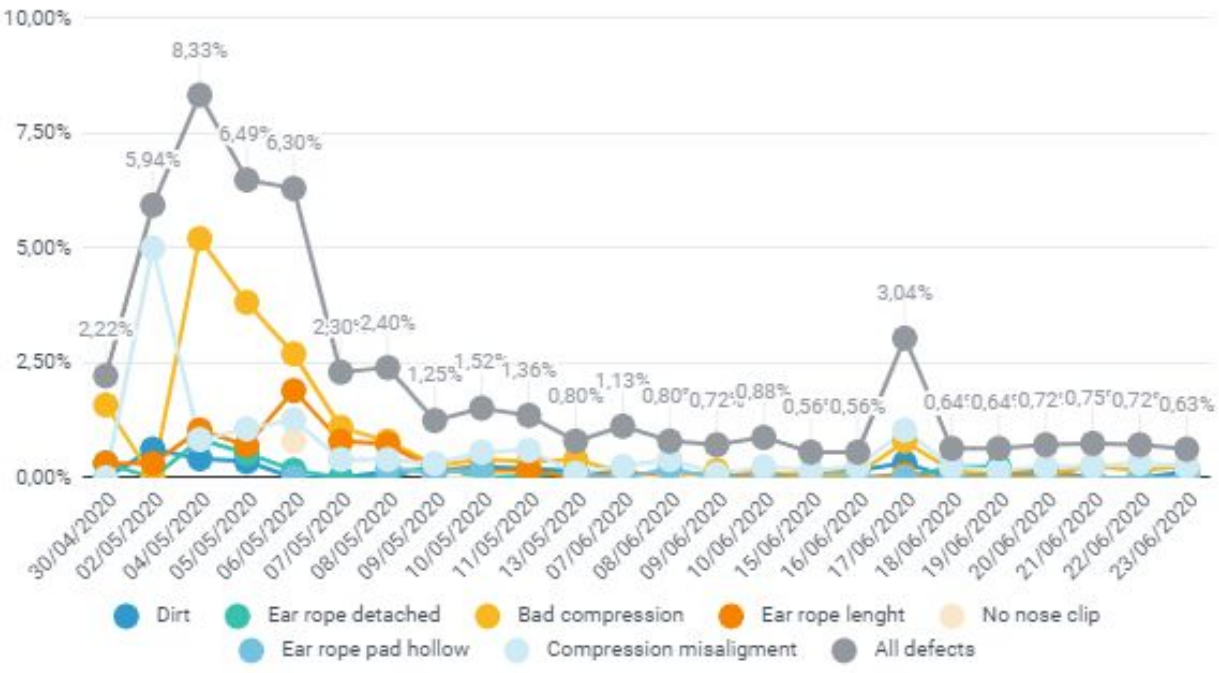
# 4. Continuous improvement

With each result of the inspections during production, **we work with the supplier on an action plan** for every improvement point. We ensure that the plan is implemented on subsequent productions and **we check that these actions improve the quality** of manufacturing.

| Planning and execution of the inspections | Analysis of results and action taking | Consolidation and checking of the results |
|---|---|---|

This graph from one of our suppliers shows how, after implementing our improvement plan on May 7th, it began to experience a generalised drop in the percentage of defects.



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# 5. Traceability control and change management

We are highly familiar with the production configuration and we store all the information that allows **any potential incident to be traced**. We also control any changes made to the manufacturing configuration (ECR) or the product so as to identify which batches would be affected and from which point.

Star Care

## 6. External inspection

Our products undergo a second quality control through Western certification companies such as Bureau Veritas and SGS. What's more, we periodically submit our criteria to your audit and inspection so that they are continuously updated.

## 7. Laboratory testing

Our products undergo external inspection at leading industry laboratories in China and Spain. It is then verified that **they meet the minimum requirements,** such as the filtration test, breathability test or the materials used.

Máquina de test de filtración FPE

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## Guaranteed delivery

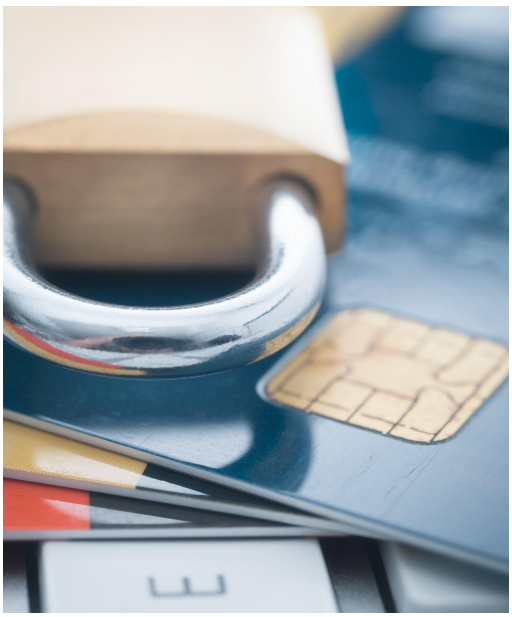
### We offer three logistical options:

1. **Delivered Duty Paid** (DDP): delivery of the goods to the agreed destination, cleared for import and ready to be unloaded.
2. **Delivered at Place Unloaded** (DPU): delivery of the goods at the established point of unloading (port or terminal).
3. **Free Carrier** (FCA): delivery to the carrier or person of your choice at Shenzhen or Canton and loading of the goods onto your means of transport.

## Financial security

We accept **verified letter of credit payments** (funds are only released upon provision of the documents and certifications for the masks) and **payment by bank transfer**.

**Accepted currencies**: AUD, CAD, CHF, EUR, GBP, HKD, JPY, NZD, SGD, USD, CNH, DKK, NOK y SEK.



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# Protective wear

**FFP2 mask**
**Ear straps**

Star Care

# FFP2

## Filtration face mask

> 98% filtration of particulate aerosols


## Technical information

Product name: Filtering half mask

Classification: FFP2 - NR (non-reusable)

Model: MSH

BFE: > 98 %

PFE: > 94 % (>98% NaCl aerosol sprays)

Size: 157 mm x 107 mm

Standard: EN 149:2001 + A1:2009

Composition: 66.7% non-woven fabric, 33.3% melt-blown non-woven fabric

Allergy warning: Non-woven textile

Expiration time: Two years if stored under the specified conditions

## Specifications

Designed for **face perfect fit**

**High breathability**

**Doble welding** that guarantees the resistance of the cords up to 25 newtons

With cord stoppers for **size regulation**

**Ear saver** included

**Individual packaging including:**

- Reusable mask bag with ziplock
- Time tracker to accurately control of the maximum hours of use
- Name tag for the owner
- Ventilation system

## Fitting instructions

1. Hold the mask with one hand, place it on your face, covering nose and chin. Pull the top strap over your head. and pass the lower strap behind your head and place it on the nape of the neck.
2. Pull the top strap over your head.
3. Pass the lower strap behind your head and place it on the nape of the neck. Adjust the cord stopper for perfect fit.
4. Using both hands, adjust the nose clip to the shape of the nose and ensure that the edges of the mask are in direct contact with the face.
5. Fit testing for leaks. Allows you to check that the mask is fitted correctly. To do this, cover the mask with both hands and exhale with force. If any leaks are detected at the edges, you will need to adjust the position of the mask against the face, readjust the nose clip and/or the tensile position of the elastic straps. Repeat this process until no leaks are detected.

CE 2163

EN 149:2001 + A1:2009

**FFP2 mask**
**Ear straps**

Star Care

# FFP2

## Filtration face mask

> 98% filtration of particulate aerosols


## Important information

- NR equipment must not be used for more than one shift.
- Use in accordance with the manufacturer's recommendations, following the instructions on the label.
- These masks do not provide oxygen.
- Not to be used in environments with low oxygen concentration or poor ventilation.
- The presence of special facial features, abundant facial hair or glasses could hinder correct fitting of the mask.
- Keep away from heat sources.
- Indoor storage with less than 80% humidity, free from corrosive gases and well ventilated.

## Individual bag specifications

Quantity: 1 unit/bag
Dimensions: 130 x 205 mm
Weight: 12 g

SKU: MASK-ST-00029.0001

8 436592 290444

SKU: MASK-ST-00013.0001

8 436592 290116

## 10 pcs box specifications

Quantity: 10 units (individual bags)/box
Dimensions: 131 x 210 x 45 mm
Weight: 153 g

SKU: MASK-ST-00029.0010

8 436592 290512

SKU: MASK-ST-00009.0010

8 436592 290314

## Master carton specifications

Quantity: 60 box/master carton
Total quantity: 600 units
Dimensions: 485 x 415 x 444 mm
Weight: 10.2 kg

CE 2163

EN 149:2001 + A1:2009

**FFP2 mask**
**Neck straps**

Star Care

# FFP2

## Filtration face mask

> 98% filtration of particulate aerosols


## Technical information

Product name: Filtering half mask

Classification: FFP2 - NR (non-reusable)

Model: MSH

BFE: > 98 %

PFE: > 94 % (>98% NaCl aerosol sprays)

Size: 157 mm x 107 mm

Standard: EN 149:2001 + A1:2009

Composition: 66.7% non-woven fabric, 33.3% melt-blown non-woven fabric

Allergy warning: Non-woven textile

Expiration time: Two years if stored under the specified conditions

## Specifications

**Neck straps** for maximum comfort

Designed for **face perfect fit**

**High breathability**

**Doble welding** that guarantees the resistance of the cords up to 25 newtons

With cord stoppers for **size regulation**

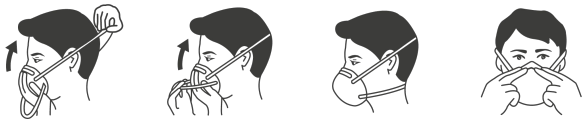
**Ear saver** included

**Individual packaging including:**

- Reusable mask bag with ziplock
- Time tracker to accurately control of the maximum hours of use
- Name tag for the owner
- Ventilation system

## Fitting instructions

1. Hold the mask with one hand, place it on your face, covering nose and chin.
2. Pull the top strap over your head.
3. Pass the lower strap behind your head and place it on the nape of the neck. Adjust the cord stopper for perfect fit.
4. Using both hands, adjust the nose clip to the shape of the nose and ensure that the edges of the mask are in direct contact with the face.
5. Fit testing for leaks. Allows you to check that the mask is fitted correctly. To do this, cover the mask with both hands and exhale with force. If any leaks are detected at the edges, you will need to adjust the position of the mask against the face, readjust the nose clip and/or the tensile position of the elastic straps. Repeat this process until no leaks are detected.



CE 2163

EN 149:2001 + A1:2009

**FFP2 mask**
**Neck straps**

Star Care

# FFP2

## Filtration face mask

> 98% filtration of particulate aerosols


## Important information

- NR equipment must not be used for more than one shift.
- Use in accordance with the manufacturer's recommendations, following the instructions on the label.
- These masks do not provide oxygen.
- Not to be used in environments with low oxygen concentration or poor ventilation.
- The presence of special facial features, abundant facial hair or glasses could hinder correct fitting of the mask.
- Keep away from heat sources.
- Indoor storage with less than 80% humidity, free from corrosive gases and well ventilated.

## Individual bag specifications

Quantity: 1 unit/bag
Dimensions: 130 x 205 mm
Weight: 12 g

SKU: MASK-ST-00033.0001

8 436592 290635

SKU: MASK-ST-00019.0001

8 436592 290208

## 10 pcs box specifications

Quantity: 10 units (individual bags)/box
Dimensions: 131 x 210 x 45 mm
Weight: 153 g

SKU: MASK-ST-00033.0010

8 436592 290642

SKU: MASK-ST-00019.00010

8 436592 290628

## Master carton specifications

Quantity: 60 box/master carton
Total quantity: 600 units
Dimensions: 485 x 415 x 444 mm
Weight: 10.2 kg

CE 2163

EN 149:2001 + A1:2009

Star Care

# FFP2

## Filtration face mask

## Suitable for children's use (6 - 12 years)


### Technical information

Product name: Filtering half mask

Classification: FFP2 - NR (non-reusable)

Model: STC-F2-01

BFE: > 98 %

PFE: > 94 % (>98% NaCl aerosol sprays)

Size: 138 mm x 97 mm (6-12 years)

Standard: EN 149:2001 + A1:2009

Composition: 66.7% non-woven fabric, 33.3% melt-blown non-woven fabric

Allergy warning: Non-woven textile

Expiration time: Two years if stored under the specified conditions

### Specifications

**Neck straps** for maximum comfort

Designed for **face perfect fit**

**High breathability**

**Doble welding** that guarantees the resistance of the cords up to 25 newtons

With cord stopper for **size regulation**

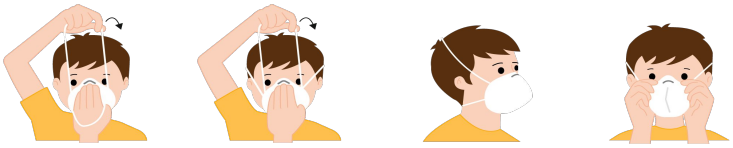
**Ear saver** included

**Individual packaging including:**

- Reusable mask bag with ziplock
- Time tracker to accurately control of the maximum hours of use
- Name tag for the owner
- Ventilation system

### Fitting instructions

1. Hold the mask with one hand, place it on your face, covering nose and chin.
2. Pull the top strap over your head.
3. Pass the lower strap behind your head and place it on the nape of the neck. Adjust the cord stopper for perfect fit.
4. Using both hands, adjust the nose clip to the shape of the nose and ensure that the edges of the mask are in direct contact with the face.
5. Fit testing for leaks. Allows you to check that the mask is fitted correctly. To do this, cover the mask with both hands and exhale with force. If any leaks are detected at the edges, you will need to adjust the position of the mask against the face, readjust the nose clip and/or the tensile position of the elastic straps. Repeat this process until no leaks are detected.



CE 0370

EN 149:2001 + A1:2009

Star Care

# FFP2

## Filtration face mask

## Suitable for children's use (6 - 12 years)


### Important information

- NR equipment must not be used for more than one shift.
- Use in accordance with the manufacturer's recommendations, following the instructions on the label.
- These masks do not provide oxygen.
- Not to be used in environments with low oxygen concentration or poor ventilation.
- The presence of special facial features, abundant facial hair or glasses could hinder correct fitting of the mask.
- Keep away from heat sources.
- Indoor storage with less than 80% humidity, free from corrosive gases and well ventilated.

### Individual bag specifications

Quantity: 1 unit/bag
Dimensions: 130 x 205 mm
Weight: 12 g

SKU: MASK-ST-00031.0001

8 436592 290499

### 10 pcs bag specifications

Quantity: 10 units (individual bags)/bag
Dimensions: 210 x 132 x 40 mm
Weight: 130 g

SKU: MASK-ST-00031.0010

8 436592 290505

### Master carton specifications

Quantity: 60 box/master carton
Total quantity: 600 units
Dimensions: 485 x 415 x 444 mm
Weight: 10.2 kg

CE 0370

EN 149:2001 + A1:2009

Star Care

# FFP3

## Filtration face mask

> 99% filtration of particulate aerosols


## Technical information

Product name: Filtering half mask

Classification: FFP3 - NR (non-reusable)

Model: MSH

Size: 156 mm x 118 mm

Standard: EN 149:2001 + A1:2009

Composition: 66.7% non-woven fabric, 33.3% melt-blown non-woven fabric

Allergy warning: Non-woven textile

Expiration time: Two years if stored under the specified conditions

## Specifications

**Anti-fog design** and face perfect fit

**High breathability**

**Doble welding** that guarantees the resistance of the cords up to 25 newtons

With cord stoppers for **size regulation**

**Ear saver** included

**Individual packaging including:**

- Reusable mask bag with ziplock
- Time tracker to accurately control of the maximum hours of use
- Name tag for the owner
- Ventilation system

## Fitting instructions

1. Hold the mask in one hand with the nose clip towards your fingers and the straps hanging free.
2. Place the mask over the face, fully covering the nose and mouth. The nose clip must be over the nose.
3. Using one hand, hold the mask against the chin. Pull the strap and place it behind your ears.
4. Using both hands, adjust the nose clip to the shape of the nose and ensure that the edges of the mask are in direct contact with the face.
5. Fit testing for leaks. Allows you to check that the mask is fitted correctly. To do this, cover the mask with both hands and exhale with force. If any leaks are detected at the edges, you will need to adjust the position of the mask against the face, readjust the nose clip and/or the tensile position of the elastic straps. Repeat this process until no leaks are detected.

CE 0370

EN 149:2001 + A1:2009

Star Care

# FFP3

## Filtration face mask

> 99% filtration of particulate aerosols


## Important information

- NR equipment must not be used for more than one shift.
- Use in accordance with the manufacturer's recommendations, following the instructions on the label.
- These masks do not provide oxygen.
- Not to be used in environments with low oxygen concentration or poor ventilation.
- The presence of special facial features, abundant facial hair or glasses could hinder correct fitting of the mask.
- Keep away from heat sources.
- Indoor storage with less than 80% humidity, free from corrosive gases and well ventilated.

## Individual bag specifications

Quantity: 1 unit/bag
Dimensions: 205 x 130 mm
weight: 14 g

SKU: MASK-ST-00024.0001

8 436592 290369

## 10 pcs bag specifications

Quantity: 10 units (individual bag)/bag
Dimensions: 131 x 210 x 60 mm
Weight: 177 g

SKU: MASK-ST-00024.0010

8 436592 290352

## Master carton specifications

Quantity: 60 box/master carton
Total quantity: 600 units
Dimensión: 635 x 415 x 444 mm
Weight: 11.6 Kg

CE 0370

EN 149:2001 + A1:2009

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# Surgical face mask
# Type IIR (BFE ≥ 98%)

## Technical information

Typology: Medical face mask (Type IIR)

Model: 175 mm x 94 mm

Standard: EN 14683-2019 + AC:2019

Size: 175 mm x 94 mm

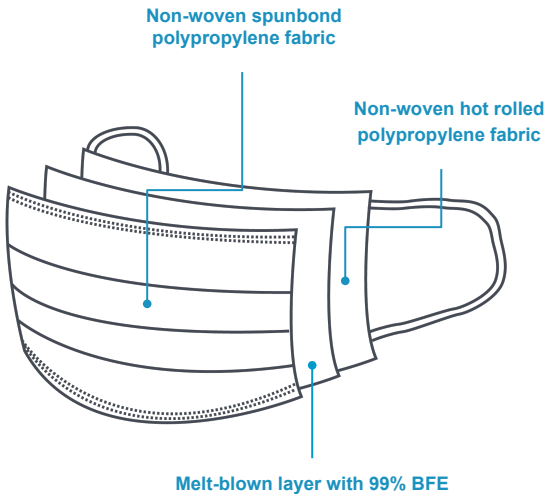
Bacterial filtration efficiency: ≥ 98%

Features: Type IIR: maximum surgical quality
Splash resistant

Structure: mask body, nose clip and mask belt

Validity period: 24 months

Allergy warning: Non-woven textile




## Fitting instructions

1. With the blue side facing outwards, place it over the nose and mouth, with the nose clip facing upwards. Then place the loops behind the ears.
2. Gently press on the nose clip in order to adjust it to the nose.
3. Pull the lower part of the mask so that it is beneath the chin and check that it fits well.

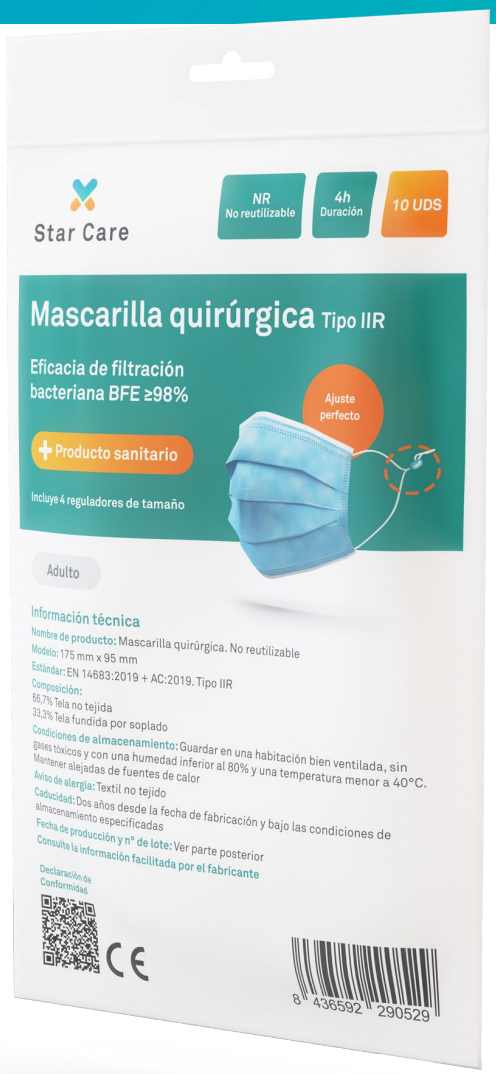
## Important information

- Hypoallergenic waterproof polypropylene material, including flexible nasal clip.
- CE Test Report issued by TÜV SUD.
- Conditions for storage: To be stored in an area with relatively low humidity, free from corrosive gases and well ventilated, avoiding high temperatures (>40°C).

CE

Star Care

# Surgical face mask
# Type IIR (BFE ≥ 98%)





CE

Star Care

# Surgical face mask
# Type IIR (BFE ≥ 98%)


| CHARACTERISTICS | STANDARD | RESULTS |
|---|---|---|
| Bacterial Filtration Efficiency (BFE) | EN 14683:2019+AC:2019 | BFE > 99.4% |
| Differential pressure (ΔP) | EN 14683:2019+AC:2019 | ΔP < 32.4 Pa/cm$^2$ |
| Microbial cleaning | EN 14683:2019+AC:2019 | CFU/g < 20 |
| Synthetic blood penetration | ISO 22609:2004 | Not detected |

Source: Test Report No.: 60379483001 (TÜV SÜD)

## 10 pcs bag specifications

Quantity: 10 units/bag
Dimensions: 240 x 135 x 23 mm
Weight: 36 g

## Master carton specifications

Quantity: 100 bags/master carton
Total quantity: 1000 units
Dimensions: 540 x 420 x 290 mm
Weight: 5.5 kg

SKU: MASK-ST-00032.0010

8 436592 290529

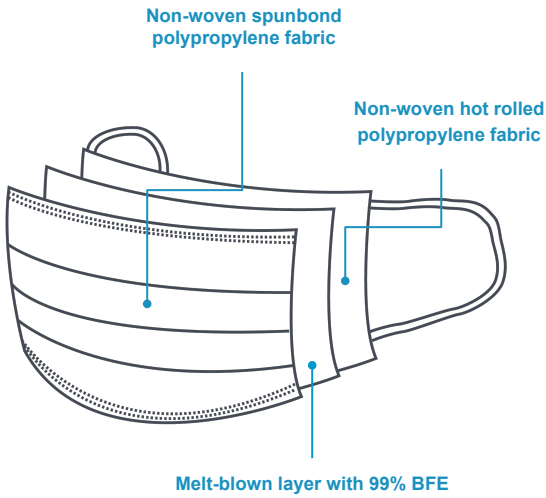
CE

Star Care

# Surgical face mask
# Type IIR (BFE ≥ 98%)
# Black

## Technical information

Typology: Medical face mask (Type IIR)
Model: 175 mm x 94 mm
Standard: EN 14683-2019 + AC:2019
Bacterial filtration efficiency: ≥ 98%
Features:
Type IIR: maximum surgical quality
Splash resistant
Structure: mask body, nose clip and mask belt
Validity period: 24 months
Allergy warning: Non-woven textile




## Fitting instructions

1. With the logo facing outwards, place the mask over the nose and mouth, with the nose clip facing upwards. Then place the loops behind the ears.
2. Gently press on the nose clip in order to adjust it to the nose.
3. Pull the lower part of the mask so that it is beneath the chin and check that it fits well.

## Important information

- Hypoallergenic waterproof polypropylene material, including flexible nasal clip.
- CE Test Report issued by TÜV SUD.
- Conditions for storage: To be stored in an area with relatively low humidity, free from corrosive gases and well ventilated, avoiding high temperatures (>40°C).

CE

Star Care

# Surgical face mask
# Type IIR (BFE ≥ 98%)
# Black



CE

Star Care

# Surgical face mask
# Type IIR (BFE ≥ 98%)
# Black


| CHARACTERISTICS | STANDARD | RESULTS |
|---|---|---|
| Bacterial Filtration Efficiency (BFE) | EN 14683:2019+AC:2019 | TBC |
| Differential pressure (ΔP) | EN 14683:2019+AC:2019 | TBC |
| Microbial cleaning | EN 14683:2019+AC:2019 | TBC |
| Synthetic blood penetration | ISO 22609:2004 | TBC |

## 10 pcs bag specifications

Quantity: 10 units/bag
Dimensions: 240 x 135 x 23 mm
Weight: 36 g

## Master carton specifications

Quantity: 100 bags/master carton
Total quantity: 1000 units
Dimensions: 540 x 420 x 290 mm
Weight: 5.5 kg

SKU: MASK-ST-00038.0010

8 436592 290901

CE

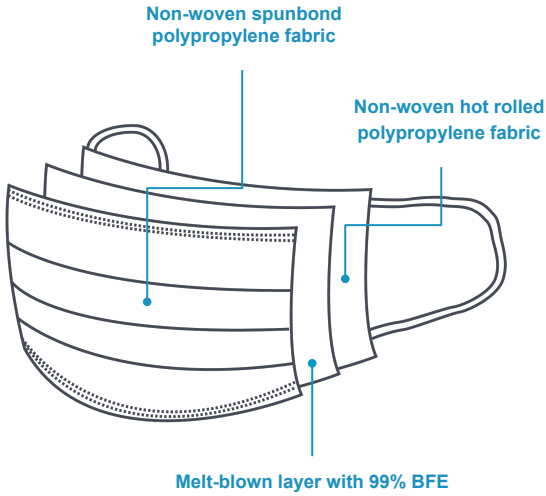
Star Care

# Surgical face mask Type IIR (BFE ≥ 98%) Kids

From 6-9 years

## Información técnica

Typology: Medical face mask (Type IIR)
Model: 150 mm x 65 mm
Standard: EN 14683-2019 + AC:2019
Size: 150 mm x 65 mm (6-9 years)
Bacterial filtration efficiency: ≥ 98%
Features:
Type IIR: maximum surgical quality
Splash resistant
Structure: Mask body, nose clip and mask belt
Validity period: 24 months
Allergy warning: Non-woven textile




## Fitting instructions

1. With the blue side facing outwards, place it over the nose and mouth, with the nose clip facing upwards. Then place the loops behind the ears.
2. Gently press on the nose clip in order to adjust it to the nose.
3. Pull the lower part of the mask so that it is beneath the chin and check that it fits well.

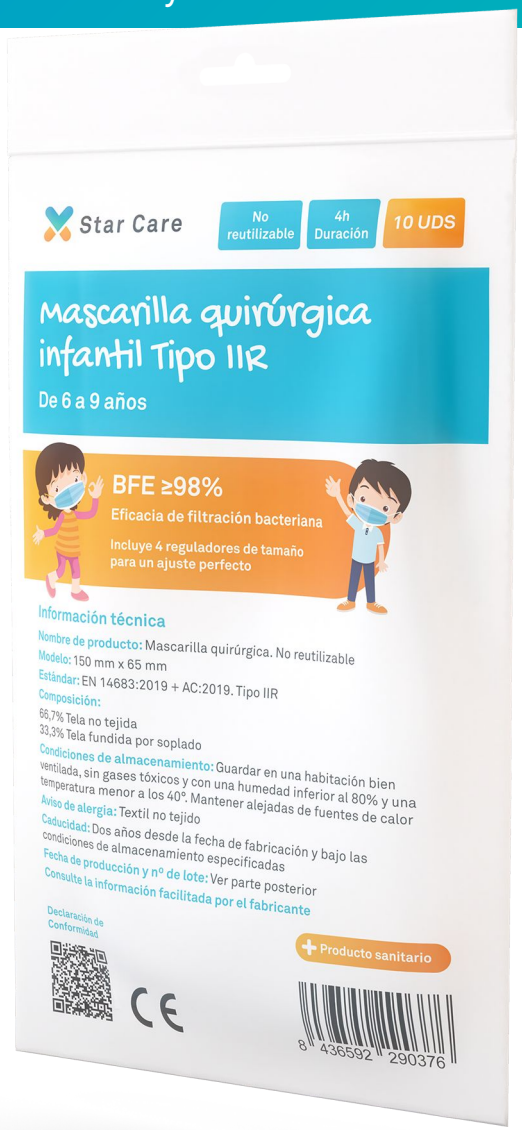
## Important information

- Hypoallergenic waterproof polypropylene material, including flexible nasal clip.
- CE Test Report issued by TÜV SUD.
- Conditions for storage: To be stored in an area with relatively low humidity, free from corrosive gases and well ventilated, avoiding high temperatures (>40ºC).

Star Care

# Surgical face mask
# Type IIR (BFE ≥ 98%)
# Kids

From 6-9 years





CE

Star Care

# Surgical face mask Type IIR (BFE ≥ 98%) Kids

From 6-9 years


| CHARACTERISTICS | STANDARD | RESULTS |
|---|---|---|
| Bacterial Filtration Efficiency (BFE) | EN 14683:2019+AC:2019 | BFE > 99.4% |
| Differential pressure (ΔP) | EN 14683:2019+AC:2019 | ΔP < 32.4 Pa/cm$^2$ |
| Microbial cleaning | EN 14683:2019+AC:2019 | CFU/g < 20 |
| Synthetic blood penetration | ISO 22609:2004 | Not detected |

Source: Test Report No.: 60379483001 (TÜV SÜD)

## 10 pcs bag specifications

Quantity: 10 units/bag
Dimensions: 210 x 120 x 23 mm
Weight: 25 g

## Master carton specifications

Quantity: 100 bags/master carton
Total quantity: 1000 units
Dimensions: 520 x 370 x 250 mm
Weight: 4.8 kg

SKU: MASK-ST-00025.0010

6 - 9 years

8 436592 290376

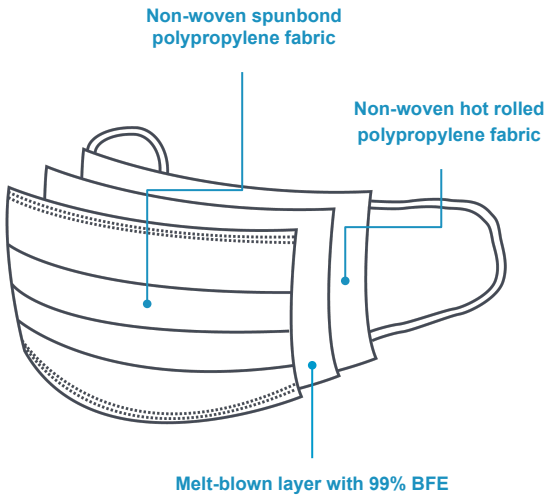
CE

Star Care

# Disposable face mask (BFE ≥ 98%)

## Technical information

Typology: Disposable face mask
Model: 175 mm x 94 mm
Standard: EN 14683-2019 + AC:2019
Size: 175 mm x 94 mm
Bacterial filtration efficiency: ≥ 98%
Features: Splash resistant
Structure: mask body, nose clip and mask belt
Validity period: 24 months
Allergy warning: Non-woven textile




## Fitting instructions

1. With the blue side facing outwards, place it over the nose and mouth, with the nose clip facing upwards. Then place the loops behind the ears.
2. Gently press on the nose clip in order to adjust it to the nose.
3. Pull the lower part of the mask so that it is beneath the chin and check that it fits well.

## Important information

- Hypoallergenic waterproof polypropylene material, including flexible nasal clip.
- CE Test Report issued by Intertek (No.: PRTT00078126, 01/10/2020).
- Conditions for storage: To be stored in an area with relatively low humidity, free from corrosive gases and well ventilated, avoiding high temperatures (>40ºC).

Star Care

# Disposable face mask (BFE ≥ 98%)


| CHARACTERISTICS | STANDARD | RESULTS |
|---|---|---|
| Bacterial Filtration Efficiency (BFE) | EN 14683:2019+AC:2019 | BFE = 98.5% |
| Differential pressure (ΔP) | EN 14683:2019+AC:2019 | ΔP = 32.4 Pa/cm$^2$ |

Fuente: Test Report No.: PRTT00078126, Intertek, 01/10/2020

## 10 pcs pack specifications

Quantity: 10 units/bag

Dimensions: 240 x 135 x 23 mm
Weight: 36 g

## Master carton specifications

Quantity: 100 bags/master carton
Total quantity: 1000 units
Dimensión: 540 x 420 x 290 mm
Peso: 5.5 kg

SKU: MASK-ST-00027.0010

8 436592 290413

cantabria labs
SPAIN

Star Care

# Hydroalcoholic hand sanitiser gel 100 ml


- Manufacturer Cantabria Labs, skincare product specialist via the prestigious brand names Heliocare, Endocare, Neostrata, Dermacare, Neoretin or Radiocare.
- Hydroalcoholic hand sanitiser gel for proper and thorough cleaning of both hands and contact surfaces used every day.
- Efficient sanitisation thanks to its optimised formula with 70% v/v alcohol content.
- It contains glycerine to maintain water balance in the skin and to minimise the damage resulting from continuous use of alcohol, providing comfort and moisture without leaving residue.

**SKU: GEL-ST-00001.0100**

**EAN: 8436574361278**

## Composition:

1. Alcohol Denat (70% v/v)
2. Phenoxyetanol (0.9% p/p)
3. Excipients c.s.p 100%

## Technical information:

1. 100 ml: PET bottle with flip-top lid for easy dispensing
2. CPNP registration 3297893
3. PAO / Validity period: Not applicable according to the regulation (CE) Nº 1223/2009

## Application and mode of use:

- EXTERNAL USE. Do not ingest. Avoid contact with the eyes and mucus membranes. Sanitiser for hands, utensils and contact surfaces.
- For correct usage, it should be applied to clean and dry healthy skin. Massage into the entire area of the hands, including between the fingers and allow to dry naturally. Do not rinse.

## PACK / PALLET SPECIFICATIONS

- **Quantity** 34 pcs/pack
- **Dimensions:** 275 x 200 x 125 mm
- **Weight:** 3.62 kg

- **Quantity:** 112 packs/pallet
- **Total quantity:** 3808 pcs
- **Dimensions:** 1200 x 800 x 1270 mm
- **Pallet weight:** 431 kg

Star Care

# Certificates

Star Care

# FFP2 mask

## Certificate

# FFP2 mask

Star Care

## Declaration of Conformity

### EU DECLARATION OF CONFORMITY

This Declaration of Conformity, issued under the sole responsibility of the manufacturer, **Huizhou Hengda Innovation Communication Equipment Co., Ltd.**, located at Building A, Wanli Industrial Co., Ltd., Dalongkeng, Ganpo, Zhenlong Town, Huiyang District, Huizhou City, Guandgdong Province, China,

**HEREBY CERTIFIES**

that the following personal protective equipment (PPE)

Model: MSH

Product description: FFP2 filtration mask

complies with the demands of Regulation (EU) 2016/425 of 9 March 2016 on personal protective equipment, including the essential health and safety requirements specified in Annex II, and of the national standards transposing the following harmonised European standards:

**EN 149:2001+A1:2009**

Furthermore, the model is identical to the PPE subject to the EU Type Examination (Module B of Regulation (EU) 2016/425) referred to in certificate Nº:

**CE 2163-PPE-707 (Date of issue: 04/06/2020)**

Issued by:

Universal Certification and Surveillance Service Trade Ltd. Co. (NB 2163)

Necip Fazil Bulvari Keyap Sitesi E2 Blok No: 44/84 Yukari Dudullu

Ümraniye-Istanbul

Turkey

The above model is subject to the conformity assessment procedure to type based on internal production control plus supervised product checks at random intervals (Module C2), according to Regulation (EU) 2016/425, under the supervision of the Notified Body Universal Certification and Surveillance Services Trade Co. (NB 2163)

Signed for and on behalf of:

Signed: Jacky Wang

Name: Jacky Wang

Position: CEO

Place and date: HUIZHOU ,CHINA 12th JUNE , 2020

# FFP2 mask

Star Care

## CE certificate

UNIVERSAL

Verify the validity with the QR code

UNIVERSAL
CERTIFICATION

NB 2163

# EU TYPE EXAMINATION CERTIFICATE

**Certificate No: 2163-PPE-707**

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

**Huizhou Hengda Innovation Communication Equipment Co., Ltd.**

Building A, Wanli Industrial Co., Ltd., Dalongkeng, Ganpo, Zhenlong Town, Huiyang District, Huizhou City, Guangdong Province, China

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:** KSA **Model:** MSH
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 **04/06/2020** 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

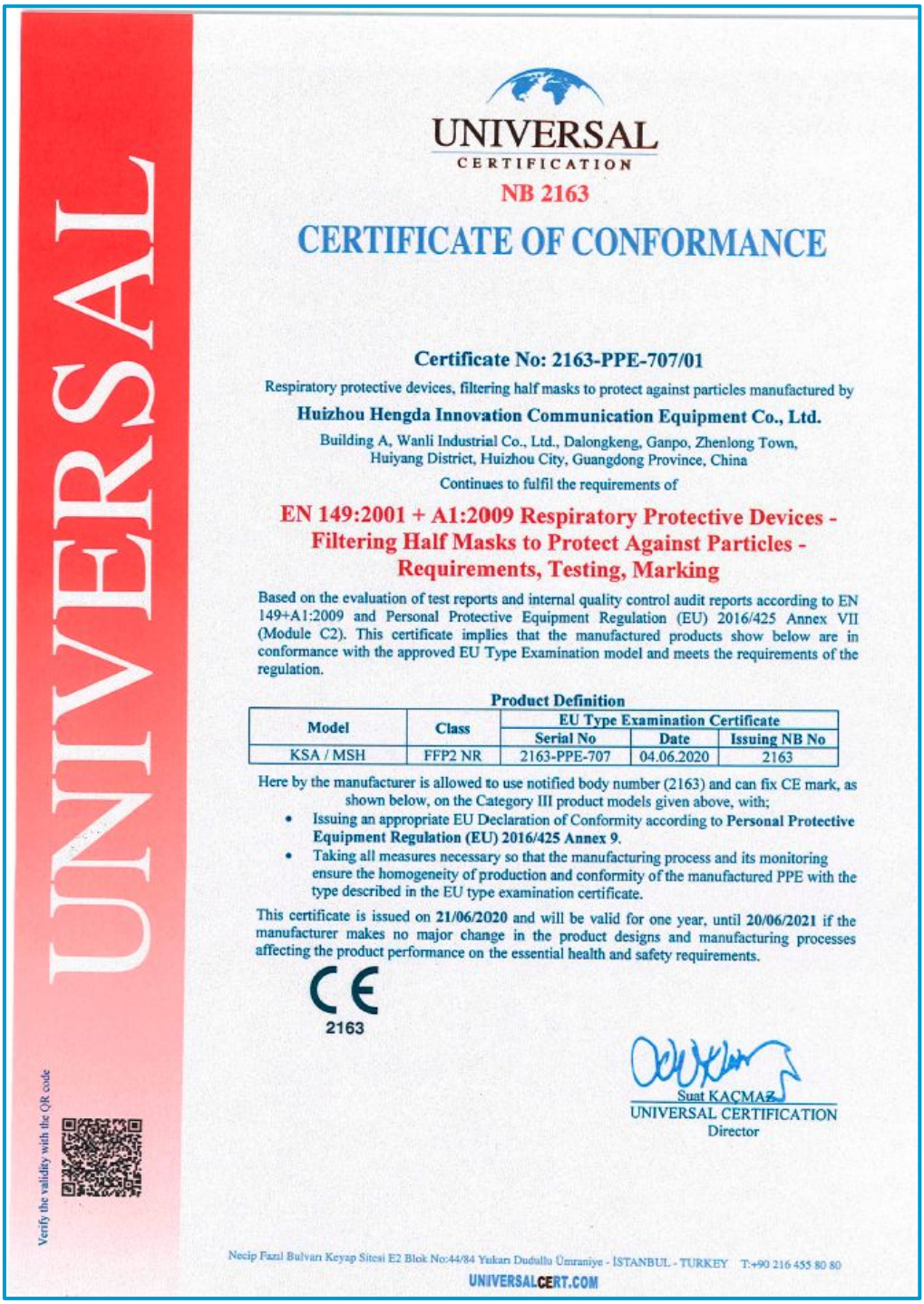
Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye - İSTANBUL - TURKEY T:+90 216 455 80 80

UNIVERSALCERT.COM

# FFP2 mask

Star Care

## CE certificate



UNIVERSAL

UNIVERSAL
CERTIFICATION
NB 2163

# CERTIFICATE OF CONFORMANCE

**Certificate No: 2163-PPE-707/01**

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

**Huizhou Hengda Innovation Communication Equipment Co., Ltd.**

Building A, Wanli Industrial Co., Ltd., Dalongkeng, Ganpo, Zhenlong Town, Huiyang District, Huizhou City, Guangdong Province, China

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 |
| KSA / MSH | FFP2 NR | 2163-PPE-707 | 04.06.2020 | 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 **21/06/2020** and will be valid for one year, until **20/06/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety 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

UNIVERSALCERT.COM

Star Care

# FFP2 mask
# Suitable for children's use (6 to 12 years)

## Certificate

# FFP2 mask
# Suitable for children's use (6 to 12 years)

Star Care

## Declaration of Conformity

This Declaration of Conformity, issued under the sole responsibility of the manufacturer, **Star TIC Innovación S.A.**, located at Calle Estrasburgo, 8 28232 Las Rozas de Madrid, Madrid (Spain),,

**HEREBY CERTIFIES**

that the following personal protective equipment (PPE)

Model: STC-F2-01

Product description: FFP2 NR filtration mask

complies with the demands of Regulation (EU) 2016/425 of 9 March 2016 on personal protective equipment, including the essential health and safety requirements specified in Annex II, and of the national standards transposing the following harmonised European standards:

**EN 149:2001+A1:2009**

Furthermore, the model is identical to the PPE subject to the EU Type Examination (Module B of Regulation (EU) 2016/425) referred to in certificate Nº:

**0370-4838-PPE/B**

Issued by:

LGAI Technological Center, S.A. (APPLUS) (NB 0370)

Campus UAB – Ronda de la Font del Carme, s/n

08193 Bellaterra (Barcelona)

Spain

The above model is subject to the conformity assessment procedure to type based on internal production control plus supervised product checks at random intervals (Module C2), according to Regulation (EU) 2016/425, under the supervision of the Notified Body LGAI Technological Center, S.A. (APPLUS) (NB 0370)

Signed for and on behalf of:

Signed:

Name: Alberto Méndez Peydro

Position: President

Place and date: 10/12/2020

# FFP2 mask
# Suitable for children's use (6 to 12 years)

Star Care

## CE certificate

LGAI Technological Center, S.A. (APPLUS)
Campus UAB - Ronda de la Font del Carme s/n 08193
Bellaterra (Barcelona)
T +34 93 567 20 00
www.appluslaboratories.com

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CE

Notified Body No. 0370

ENAC CERTIFICACIÓN Nº 12/C-PR054

# CERTIFICADO DE EXAMEN UE DE TIPO
## *EU-TYPE EXAMINATION CERTIFICATE*

No. 0370-4838-PPE/B

| | |
|---|---|
| **ORGANISMO NOTIFICADO Nº** *NOTIFIED BODY NUMBER* | **0370 - LGAI TECHNOLOGICAL CENTER** (APPLUS) |
| **SOLICITANTE / FABRICANTE** *APPLICANT / MANUFACTURER* | **Star TIC Innovación, S.A.** C/ Sofía, 10, 28232 Las Rozas de Madrid, España |
| **PLANTA DE PRODUCCIÓN** *PRODUCTION SITE* | **Huizhou Hengda Innovation Communication Equipment Co., Ltd.** Building A, Wanli Industrial Co., Ltd., Dalongkeng, Ganpo, Zhenlong Town, Huiyang District, Huizhou City, Guangdong, China. |
| **REGLAMENTO DE APLICACIÓN PARA DAR LA CONFORMIDAD** / *APPLICABLE REGULATION TO GIVE CONFORMITY:* **REGLAMENTO (UE) 2016/425 SOBRE LOS EQUIPOS DE PROTECCIÓN INDIVIDUAL** *REGULATION (EU) 2016/425 PERSONAL PROTECTIVE EQUIPMENT* | |
| **PROCEDIMIENTO DE EVALUACIÓN DE LA CONFORMIDAD** *CONFORMITY ASSESSMENT PROCEDURE* | Módulo // *Module*: **B** **EXAMEN UE DE TIPO** / *EU TYPE EXAMINATION* |
| **IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO)** *IDENTIFICATION OF THE PPE (TYPE NUMBER)* | Ref.: STC-F2-01 Filtering half mask |
| **NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI** / *PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE* | FFP2 NR |
| **NORMAS ARMONIZADAS** / *HARMONISED STANDARDS* | EN 149:2001 + A1:2009 Dispositivos de protección respiratoria. Medias máscaras filtrantes de protección contra partículas. Requisitos, ensayos, marcado. *EN 149:2001 + A1:2009 Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking* |
| **FECHA DE EMISIÓN** / *ISSUE DATE* | **26/11/2020** |
| **VALIDEZ HASTA** / *VALIDITY UNTIL* | **26/11/2025** |

El presente certificado se mantendrá vigente durante 5 años siempre que el producto descrito no sea modificado y cumpla los requisitos esenciales de salud y seguridad establecidos en el Reglamento (UE) 2016/425. Para asegurar dicho cumplimiento, este certificado deberá ir acompañado de la documentación correspondiente a la Evaluación de Conformidad con el tipo según módulo C2, D (realizada por un Organismo Notificado, según frecuencia establecida).

*This certificate will remain valid for 5 years as long as the indicated product is not modified and fulfills the essential requirements of health and safety established in (EU) Regulation 2016/425. To ensure such compliance, this certificate must be accompanied by the documentation corresponding to the Conformity Assessment to type according to C2, D(carried out by a Notified Body according, to the established frequency).*

Applus
LGAI Technological Center, S.A.
Xavier Ruiz Peña
Managing Director, Product Conformity B.U.

Este documento carece de validez sin su anexo técnico, cuyo número coincide con el del certificado.
*This document is not valid without its technical annex, whose number coincides with the number of certificate.*

Puede comprobarse la validez de este certificado en nuestra página web / *You can check the validity of this certificate on our website:*
*www.appluslaboratories.com/certified_products*

# FFP2 mask
# Suitable for children's use
# (6 to 12 years)

Star Care

## CE certificate

I.C.A.I. Technological Center, S.A. (APPLUS)
Campus UAB - Ronda de la Font del Carme s/n
08193 Bellaterra (Barcelona)
T +34 93 567 20 00
www.appluslaboratories.com

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Technical Annex Ed. 1
26/11/2020

**ANEXO TÉCNICO**
*TECHNICAL ANNEX*

**0370-4838-PPE/B**

## I. MODELOS INCLUIDOS EN EL CERTIFICADO

*REFERENCES INCLUDED IN THIS CERTIFICATE*

| | |
|---|---|
| **MARCA**<br>*BRAND* | Star Care |
| **IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO)**<br>*IDENTIFICATION OF THE PPE (TYPE NUMBER)* | Ref.: STC-F2-01<br>Filtering half mask |
| **NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI**<br>*PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE* | FFP2 NR |
| **INFORME DE ENSAYO**<br>*TEST REPORT* | S20102603601E issued by Shenzhen NTEK Testing Technology Co., Ltd. （NTEK） |

Star Care

# FFP3 masks

## Certificate

# FFP3 mask

Star Care

## Declaration of Conformity

### EU DECLARATION OF CONFORMITY

This Declaration of Conformity, issued under the sole responsibility of the manufacturer, **Huizhou Hengda Innovation Communication Equipment Co., Ltd.,** located at Building A, W'anli Industrial Co., Ltd., Dalongkeng, Ganpo, Zhenlong Town, Huiyang District, Huizhou City, Guandgdong Province, China,

**HEREBY CERTIFIES**

that the following personal protective equipment (PPE)

Model: MSH

Product description: FFP3 NR filtration mask

complies with the demands of Regulation (EU) 2016/425 of 9 March 2016 on personal protective equipment, including the essential health and safety requirements specified in Annex II, and of the national standards transposing the following harmonised European standards:

**EN 149:2001+A1:2009**

Furthermore, the model is identical to the PPE subject to the EU Type Examination (Module B of Regulation (EU) 2016/425) referred to in certificate Nº:

**0370-4360-PPE/B (Date of issue: 09/09/2020)**

Issued by:

LGAI Technological Center, S.A. (APPLUS) (NB 0370)

Campus UAB – Ronda de la Font del Carme, s/n

08193 Bellaterra (Barcelona)

Spain

The above model is subject to the conformity assessment procedure to type based on internal production control plus supervised product checks at random intervals (Module C2), according to Regulation (EU) 2016/425, under the supervision of the Notified Body 0370 LGAI Technological Center, S.A. (APPLUS). (NB 0370) with last certificate number 0370-4640-PPE/C2 (Date of issue: 22/10/2020)

Signed for and on behalf of:

Signed: Coco Ban

Name: Coco Ban

Position: Director of supply chain

Place and date: Shenzhen, 05/11/2020

# FFP3 mask

Star Care

## CE certificate

LGAI Technological Center, S.A. (APPLUS)
Campus UAB - Ronda de la Font del Carme s/n
08193 Bellaterra (Barcelona)
T +34 93 567 20 00
www.applus.com

Applus

# CERTIFICADO DE EXAMEN UE DE TIPO

## *EU-TYPE EXAMINATION CERTIFICATE*

CE

Notified Body No. 0370

ENAC CERTIFICACIÓN Nº 12/C-PR154

**No.** 0370-4360-PPE/B

| | |
|---|---|
| **ORGANISMO NOTIFICADO Nº** *NOTIFIED BODY NUMBER* | **0370 - LGAI TECHNOLOGICAL CENTER** (APPLUS) |
| **SOLICITANTE** *APPLICANT* | **Huizhou Hengda Innovation Communication Equipment Co., Ltd.** Building A, Wanli Industrial Co., Ltd, Dalongkeng,Ganpo,Zhenlong Town, Huiyang District, Huizhou City, Guangdong Province, China |
| **FABRICANTE** *MANUFACTURER* | **Huizhou Hengda Innovation Communication Equipment Co., Ltd.** Building A, Wanli Industrial Co., Ltd, Dalongkeng,Ganpo,Zhenlong Town, Huiyang District, Huizhou City, Guangdong Province, China |
| **REGLAMENTO DE APLICACIÓN PARA DAR LA CONFORMIDAD** / *APPLICABLE REGULATION TO GIVE CONFORMITY:* **REGLAMENTO (UE) 2016/425 SOBRE LOS EQUIPOS DE PROTECCIÓN INDIVIDUAL** *REGULATION (EU) 2016/425 PERSONAL PROTECTIVE EQUIPMENT* | |
| **PROCEDIMIENTO DE EVALUACIÓN DE LA CONFORMIDAD** *CONFORMITY ASSESSMENT PROCEDURE* | Módulo // *Module:* **B** **EXAMEN UE DE TIPO** / *EU TYPE EXAMINATION* |
| **IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO)** *IDENTIFICATION OF THE PPE (TYPE NUMBER)* | Ref.: MSH Filtering half mask |
| **NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI** / *PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE* | FFP3 NR |
| **NORMAS ARMONIZADAS** / *HARMONISED STANDARDS* | EN 149:2001 + A1:2009 Dispositivos de protección respiratoria. Medias máscaras filtrantes de protección contra partículas. Requisitos, ensayos, marcado. *EN 149:2001 + A1:2009 Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking* |
| **FECHA DE EMISIÓN** / *ISSUE DATE* | **09/09/2020** |
| **VALIDEZ HASTA** / *VALIDITY UNTIL* | **09/09/2025** |

El presente certificado se mantendrá vigente durante 5 años siempre que el producto descrito no sea modificado y cumpla los requisitos esenciales de salud y seguridad establecidos en el Reglamento (UE) 2016/425. Para asegurar dicho cumplimiento, este certificado deberá ir acompañado de la documentación correspondiente a la Evaluación de Conformidad con el tipo según módulo C2, D (realizada por un Organismo Notificado, según frecuencia establecida).

*This certificate will remain valid for 5 years as long as the indicated product is not modified and fulfills the essential requirements of health and safety established in (EU) Regulation 2016/425. To ensure such compliance, this certificate must be accompanied by the documentation corresponding to the Conformity Assessment to type according to C2, D(carried out by a Notified Body according, to the established frequency).*

Applus
LGAI Technological Center, S.A.
Xavier Ruiz Peña
Managing Director, Product Conformity B.U.

Este documento carece de validez sin su anexo técnico, cuyo número coincide con el del certificado.
*This document is not valid without its technical annex, whose number coincides with the number of certificate.*
Puede comprobarse la validez de este certificado en nuestra página web / *You can check the validity of this certificate into our website at:* *www.appluslaboratories.com/certified_products*

# FFP3 mask

Star Care

## CE certificate

LGAI Technological Center, S.A. (APPLUS)
Campus UAB – Ronda de la Font del Carme, s/n
E - 08193 Bellaterra (Barcelona)
T +34 93 567 20 00
www.appluslaboratories.com

Applus laboratories

Technical Annex Ed. 1
09/09/2020

**ANEXO TÉCNICO**
*TECHNICAL ANNEX*

**0370-4360-PPE/B**

## I. MODELOS INCLUIDOS EN EL CERTIFICADO

*REFERENCES INCLUDED IN THIS CERTIFICATE*

| | |
|---|---|
| **MARCA**<br>*BRAND* | MSH |
| **IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO)**<br>*IDENTIFICATION OF THE PPE (TYPE NUMBER)* | Ref.: MSH<br>Filtering half mask |
| **NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI**<br>*PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE* | FFP3 NR |
| **INFORME DE ENSAYO**<br>*TEST REPORT* | S20080700801E-R1 issued by Shenzhen NTEK Testing Technology Co., Ltd. （NTEK) |

# FFP3 mask

Star Care

## CE certificate

LGAI Technological Center, S.A. (APPLUS)
Campus UAB - Ronda de la Font del Carme s/n 08193
Bellaterra (Barcelona)
T +34 93 567 20 00
www.appluslaboratories.com

Applus

CE

Organismo Notificado Nº 0370

ENAC
CERTIFICACIÓN
Nº 13/C-PR054

# CERTIFICADO DE CONFORMIDAD CON EL TIPO
# *CONFORMITY TO TYPE CERTIFICATE*

**No.** 0370-4640-PPE/C2

| | |
|---|---|
| **ORGANISMO NOTIFICADO Nº** *NOTIFIED BODY NUMBER* | **0370 - LGAI TECHNOLOGICAL CENTER** (APPLUS) |
| **SOLICITANTE / FABRICANTE** *APPLICANT / MANUFACTURER* | **Huizhou Hengda Innovation Communication Equipment Co., Ltd.** Building A, Wanli Industrial Co., Ltd, Dalongkeng,Ganpo,Zhenlong Town, Huiyang District, Huizhou City, Guangdong Province, China |
| **PLANTA DE PRODUCCIÓN** *PRODUCTION SITE* | **Huizhou Hengda Innovation Communication Equipment Co., Ltd.** Building A, Wanli Industrial Co., Ltd, Dalongkeng,Ganpo,Zhenlong Town, Huiyang District, Huizhou City, Guangdong Province, China |
| **REGLAMENTO DE APLICACIÓN PARA DAR LA CONFORMIDAD** / *APPLICABLE REGULATION TO GIVE CONFORMITY:* **REGLAMENTO (UE) 2016/425 SOBRE LOS EQUIPOS DE PROTECCIÓ INDIVIDUAL** *REGULATION (EU) 2016/425 PERSONAL PROTECTIVE EQUIPMENT* | |
| **PROCEDIMIENTO DE EVALUACIÓN DE LA CONFORMIDAD CON EL TIPO** *CONFORMITY ASSESSMENT PROCEDURE TO TYPE* | Módulo // *Module:* **C2** **BASADA EN EL CONTROL INTERNO DE LA PRODUCCIÓN MÁS EL CONTROL SUPERVISADO DE LOS PRODUCTOS A INTERVALOS ALEATORIOS** *BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED CONTROL OF PRODUCTS AT ALEATORY INTERVALS* |
| **IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO)** *IDENTIFICATION OF THE PPE (TYPE NUMBER)* | Ref.: MSH Filtering half mask |
| **NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI** / *PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE* | FFP3 NR |
| **FECHA DE EMISIÓN** / *ISSUE DATE* | **22/10/2020** |
| **VALIDEZ HASTA** / *VALIDITY UNTIL:* | **22/10/2021** |
| El presente certificado se mantendrá vigente durante 1 año siempre que no se modifiquen las condiciones establecidas en el Certificado de Examen UE de Tipo referenciado en el Anexo. *This certificate will remain in force for 1 year as long as the conditions established in the EU Type certificate referenced in the annex are not modified.* | |

Applus
LGAI Technological Center, S.A.
Xavier Ruiz Peña
Managing Director, Product Conformity B.U.

Este documento carece de validez sin su anexo técnico, cuyo número coincide con el del certificado.
*This document is not valid without its technical annex, whose number coincides with the number of certificate.*

Puede comprobarse la validez de este certificado en nuestra página web / *You can check the validity of this certificate on our website:*
*www.appluslaboratories.com/certified_products*

# FFP3 mask

Star Care

## CE certificate

LGAI Technological Center, S.A. (APPLUS)
Campus UAB - Ronda de la Font del Carme s/n
08193 Bellaterra (Barcelona)
T +34 93 667 20 00
www.appluslaboratories.com

Applus

Technical Annex Ed. 1
22/10/2020

**ANEXO TÉCNICO**
*TECHNICAL ANNEX*

**0370-4640-PPE/C2**

## I. MODELOS INCLUIDOS EN EL CERTIFICADO

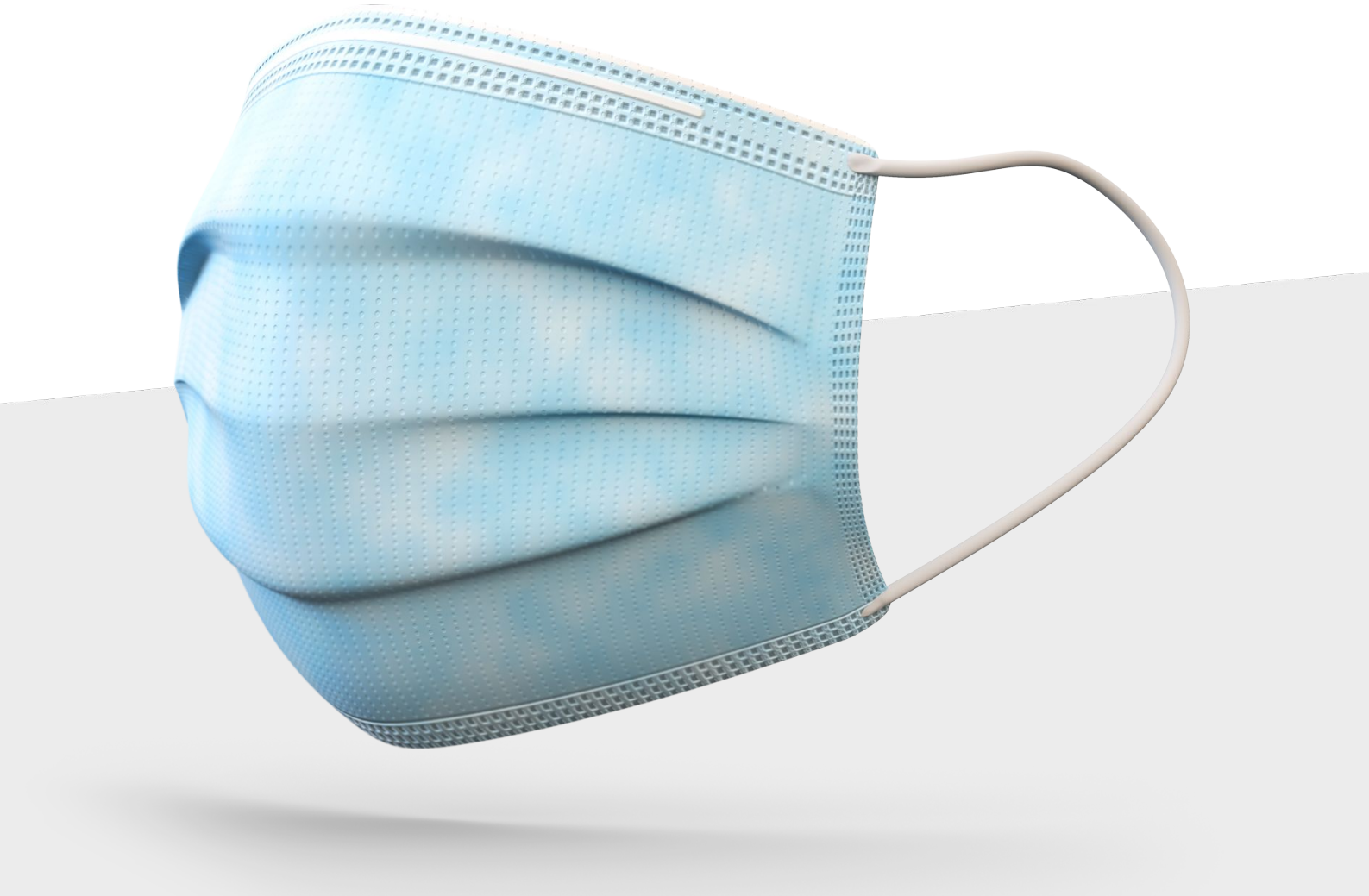
*REFERENCES INCLUDED IN THIS CERTIFICATE*

| | |
|---|---|
| **Nº CERTIFICADO DE EXAMEN UE DE TIPO**<br>*NR. EU TYPE EXAMINATION CERTIFICATE* | **0370-4360-PPE/B** |
| **EMITIDO POR**<br>*ISSUED BY* | LGAI TECHNOLOGICAL CENTER S.A. (APPLUS)<br>**(Organismo notificado nº 0370 /** *Notified Body nr. 0370*). |
| **FECHA EMISIÓN**<br>*ISSUE DATE* | 09/09/2020 |
| **VALIDEZ HASTA**<br>*VALIDITY UNTIL* | 09/09/2025 |
| **MARCA**<br>*BRAND* | kSa |
| **IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO)**<br>*IDENTIFICATION OF THE PPE (TYPE NUMBER)* | Ref.: MSH<br>Filtering half mask |
| **NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI /**<br>*PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE* | FFP3 NR |
| **INFORME DE ENSAYO DE CONFORMIDAD CON EL TIPO**<br>*CONFORMITY TO TYPE TEST REPORT* | S20080700802E issued by Shenzhen NTEK Testing Technology Co., Ltd. |

Star Care

# Surgical face mask BFE 98%

## Certificate



# Surgical mask /
# Surgical mask (Kids) BFE 98%

## Declaration of Conformity

CE

### EU Declaration OfConformity

Manufacturer **Diasia Biomedical Technology Co., Ltd.**

Address **3th B,4th Floor, Building No.4, Chuangfu Industrial Park, Xixiang Tiegang Reservoir Road, Baoan District, Shenzhen, China**

EC Representative **M/sCMC Medical Devices& Drugs S.L.**

**C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain**

**+34951214054**

Product:**Disposable Medical Mask**

Model: **175mm×94mm , 145mm×94mm , 150mm×65mm**

Classification (MDD, Annex IX): **Class IRule1**

We herewith declare that the above mentioned products meet the transposition into national law, Theprovisions of the following EC Council Directives and Standards. All supporting documentations areretained under the premises of the manufacturer. We are exclusively responsible for the DOC.

DIRECTIVES
General applicabledirectives:
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

Standards:
EN 14683:2019;
ISO 10993-5-2009;
ISO 10993-10:2010;

All applable harmonized Standards (published in the Official Journal of the European Communities)

Date CE mark wasaffixed: **May 12, 2020**
Place, Date: **Shenzhen, 12.05.2020**
Signature: Kirby Deng / General Manager
Name/Position: Kirby Deng / G.M.

# Surgical mask /
# Surgical mask (Kids) BFE 98%

## CE certificate

**Produkte**
*Products*

TÜVRheinland®

| | | | | |
|---|---|---|---|---|
| **Prüfbericht-Nr.:** *Test Report No.:* | 60379483 001 | **Auftrags-Nr.** *Order No.:* | 168265694 | Seite 1 von 12 *Page 1 of 12* |
| **Kunden-Referenz-Nr.:** *Client Reference No.:* | N/A | **Auftragsdatum:** *Order date:* | May 20, 2020 | |
| **Auftraggeber:** *Client:* | **Diasia Biomedical Technology Co., Ltd.** 3th B, 4th Floor, Building No.4, Chuangfu Industrial Park, Xixiang Tiegang Reservoir Road, Baoan District, Shenzhen, China | | | |
| **Prüfgegenstand:** *Test item:* | Disposable Medical Mask | | | |
| **Bezeichnung / Typ-Nr.:** *Identification / Type No.:* | 175mm × 94mm, 150mm × 65mm, 145mm × 94mm | | | |
| **Auftrags-Inhalt:** *Order content:* | Type test | | | |
| **Prüfgrundlage:** *Test specification:* | EN 14683:2019+AC:2019 except for clause 5.2.6 | | | |
| **Wareneingangsdatum:** *Date of receipt:* | May 20, 2020 | See Attachment: Photo documentation for details. | | |
| **Prüfmuster-Nr.:** *Test sample No.:* | 20200516 | | | |
| **Prüfzeitraum:** *Testing period:* | May 21, 2020 to Jun. 01, 2020 | | | |
| **Ort der Prüfung:** *Place of testing:* | See page 3 | | | |
| **Prüflaboratorium:** *Testing laboratory:* | TÜV Rheinland (Shenzhen) Co., Ltd. | | | |
| **Prüfergebnis*:** *Test result*:* | Pass | | | |

**geprüft von** / *tested by:*

Lucy Jiang

Jun. 28, 2020 Lucy Jiang / Assistant Project Engineer

| Datum *Date* | Name / Stellung *Name / Position* | Unterschrift *Signature* |
|---|---|---|

**kontrolliert von** / *reviewed by:*

Jun. 28, 2020 Angela Chen / Department Manager

| Datum *Date* | Name / Stellung *Name / Position* | Unterschrift *Signature* |
|---|---|---|

**Sonstiges** / *Other:*

- The test report consists of EN 14683 test report including this cover page (12 pages) and attachment: Photo documentation (9 pages).
- The Biocompatibility (clause 5.2.6) is not evaluated in this test report.

**Zustand des Prüfgegenstandes bei Anlieferung:** Prüfmuster vollständig und unbeschädigt
*Condition of the test item at delivery:* *Test item complete and undamaged*

| | | | | | |
|---|---|---|---|---|---|
| * Legende: | 1 = sehr gut | 2 = gut | 3 = befriedigend | 4 = ausreichend | 5 = mangelhaft |
| | P(ass) = entspricht o.g. Prüfgrundlage(n) | | F(ail) = entspricht nicht o.g. Prüfgrundlage(n) | N/A = nicht anwendbar | N/T = nicht getestet |
| *Legend:* | *1 = very good* | *2 = good* | *3 = satisfactory* | *4 = sufficient* | *5 = poor* |
| | *P(ass) = passed a.m. test specification(s)* | | *F(ail) = failed a.m. test specification(s)* | *N/A = not applicable* | *N/T = not tested* |



V04

TÜV Rheinland (Shenzhen) Co., Ltd., East of F/1, F/2 - F/4, Building 1, Cybio Technology Building, No. 6 Langshan No. 2 Road, North Hi-tech Industry Park, Nanshan District, Shenzhen, P.R. China
http://www.tuv.com

# Surgical mask /
# Surgical mask (Kids) BFE 98%

## CE certificate



| EN 14683:2019+AC: 2019<br>Medical face masks —<br>Requirements and test methods | |
|---|---|
| Report Reference No. ..... : | 60379483 001 |
| Date of issue..... : | See cover page |
| Total number of pages ..... : | See cover page |
| Testing Laboratory ..... : | TÜV Rheinland (Shenzhen) Co., Ltd. |
| Address..... : | 1F East & 2-4F, Cybio Technology Building No.1, No.16 Kejibei 2nd Road, High-Tech Industrial Park North Nanshan District, 518057, Shenzhen, China |
| Applicant's name ..... : | Diasia Biomedical Technology Co., Ltd. |
| Address..... : | 3th B, 4th Floor, Building No.4, Chuangfu Industrial Park, Xixiang Tiegang Reservoir Road, Baoan District, Shenzhen, China |
| Test specification: | |
| Standard ..... : | EN 14683:2019+AC:2019 |
| Test procedure..... : | Type test |
| Non-standard test method..... : | N/A |
| Test Report Form No. ..... : | EN 14683:2019+AC:2019_A |
| Test Report Form Originator ..... : | TÜV Rh (SZ) |
| Master TRF ..... : | 2020-03 |
| Test item description..... : | Disposable Medical Mask |
| Trade Mark..... : | DIAsia 德夏 |
| Manufacturer ..... : | Same as the applicant |
| Model/Type reference ..... : | 175mm × 94mm, 150mm × 65mm, 145mm × 94mm |
| Classification..... : | Type IIR |

# Surgical mask /
# Surgical mask (Kids) BFE 98%

## CE certificate



| List of Attachments (including a total number of pages in each attachment): | |
|---|---|
| Attachment – Photo Documentation (9 pages) | |
| **Summary of testing:** | |
| **Tests performed (name of test and test clause):**<br>Construction check according to:<br>Clause 5.1.1 Materials and construction<br>Clause 5.1.2 Design | **Testing location:**<br>**TÜV Rheinland (Shenzhen) Co., Ltd.**<br>1F East & 2-4F, Cybio Technology Building No.1, No.16 Kejibei 2nd Road, High-Tech Industrial Park North Nanshan District, 518057, Shenzhen, China |
| Clause 5.2.2 Bacterial filtration efficiency (BFE)<br>Clause 5.2.3 Breathability<br>Clause 5.2.4 Splash resistance<br>Clause 5.2.5 Microbial cleanliness (Bioburden) | **Pony Testing Group Shanghai Co., Ltd.**<br>2/3/4/6/F., Building 35, No.680, Guiping Road, Xuhui District, Shanghai, China |

# Surgical mask /
# Surgical mask (Kids) BFE 98%

## CE certificate



| Copy of marking plate |
| --- |
| The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.<br><br>See attachment. |

# Surgical mask /
# Surgical mask (Kids) BFE 98%

## CE certificate



**Testing**

**Date of receipt of test item(s).....:** See cover page

**Dates of tests performed .....:** See cover page

**Possible test case verdicts:**

- test case does not apply to the test object ..... : N/A
- test object does meet the requirement ..... : P (Pass)
- test object was not evaluated for the requirement .... : N/E (collateral standards only)
- test object does not meet the requirement ..... : F (Fail)

**General remarks:**

"(See Attachment #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

**Throughout this report a ☐ comma / ☒ point is used as the decimal separator.**

**Name and address of factory (ies) ..... :** Same as the applicant

**General product information:**

**1, The tested medical mask classified as type IIR.**
**2, The Biocompatibility (clause 5.2.6) is not evaluated in this test report.**
**3, The test results are for reference only. Relevant certification may be needed if the mask is intended to be sold in Europe.**
**4, Three models are identical with each other except for the size, the sizes for three models are 175mm × 94mm, 150mm × 65mm and 145mm × 94mm. All the tests are performed on model 175mm × 94mm.**

# Surgical mask /
# Surgical mask (Kids) BFE 98%

## CE certificate



| EN 14683:2019+AC:2019 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **4** | **Classification** | | **P** |
| | Medical face masks specified in this European Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant. The 'R' signifies splash resistance. | Type IIR | P |
| **5** | **Requirements** | | **P** |
| **5.1** | **General** | | **P** |
| **5.1.1** | **Materials and construction** | | **P** |
| | The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric. | 3 ply designed with two layers of non-woven fabric and one layer of melt blown fabric. | P |
| | The medical face mask shall not disintegrate, split or tear during intended use. | | P |
| | In the selection of the filter and layer materials, attention shall be paid to cleanliness. | | P |
| **5.1.2** | **Design** | | **P** |
| | The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides. | | P |
| | Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours). | With nose clip | P |
| **5.2** | **Performance requirements** | | **P** |
| **5.2.1** | **General** | | **P** |
| | All tests shall be carried out on finished products or samples cut from finished products. | | P |
| **5.2.2** | **Bacterial filtration efficiency (BFE)** | | **P** |
| | When tested in accordance with Annex B, the BFE of the medical face mask shall conform to the minimum value given for the relevant type in Table 1. | See appended table 5.2.2 | P |
| | For thick and rigid masks such as rigid duckbill or cup masks the test method may not be suitable as a proper seal cannot be maintained in the cascade impactor. In these cases, another valid equivalent method shall be used to determine the BFE. | Not such mask. | N/A |

# Surgical mask /
# Surgical mask (Kids) BFE 98%

## CE certificate



| EN 14683:2019+AC:2019 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | When a mask consists of two or more areas with different characteristics or different layer-composition, each panel or area shall be tested individually. | Same characteristics and same layer-composition declared by manufacturer. | N/A |
| | The lowest performing panel or area shall determine the BFE value of the complete mask | See above | N/A |
| 5.2.3 | **Breathability** | | P |
| | When tested in accordance with Annex C, the differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 1. | See appended table 5.2.3 | P |
| | If the use of a respiratory protective device as face mask is required in an operating theatre and/or other medical settings, it might not fulfil the performance requirements with regard to differential pressure as defined in this European Standard. In such case, the device should fulfil the requirement as specified in the relevant Personal Protective Equipment (PPE) standard(s). | | N/A |
| 5.2.4 | **Splash resistance** | | P |
| | When tested in accordance with ISO 22609:2004 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1. | See appended table 5.2.4 | P |
| 5.2.5 | **Microbial cleanliness (Bioburden)** | | P |
| | When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ⩽ 30 CFU/g tested (see Table 1). | See appended table 5.2.5 | P |
| 5.2.6 | **Biocompatibility** | | N/E |
| | According to the definition and classification in EN ISO 10993-1:2009, a medical face mask is a surface device with limited contact. | The biocompatibility is not evaluated in this test report. | N/E |
| | The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1:2009 and determine the applicable toxicology testing regime. | | N/E |
| | The results of testing should be documented according to the applicable parts of the EN ISO 10993 series. | | N/E |
| | The test results shall be available upon request. | | N/E |
| 6 | **Marking, labelling and packaging** | | P |
| | Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied. | See attachment. | P |
| | The following information shall be supplied: | | P |
| | a) number of this European Standard; | | P |

# Surgical mask /
# Surgical mask (Kids) BFE 98%

## CE certificate



| EN 14683:2019+AC:2019 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | b) type of mask (as indicated in Table 1). | | P |
| | EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered. | | P |

# Surgical mask /
# Surgical mask (Kids) BFE 98%

## CE certificate



| EN 14683:2019+AC:2019 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

| 5.2.2 | TABLE: Bacterial filtration efficiency (BFE) | | | | | | | P |
|---|---|---|---|---|---|---|---|---|
| Batch/ lot no.: | Test Specimen no.: | Dimension of the test specimen L x W (mm x mm) | test area ($cm^2$) | Flow rate (l/min) | Mean of the total plate counts of the two positive controls | Mean plate count of the negative controls | BFE for each test specimen (%) | Remarks |
| 20200516 | 1 | 164×144 | 95.0 | 28.3 | 1729 | 0 | 99.4 | -- |
| | 2 | 164×145 | 95.0 | 28.3 | | | 99.8 | -- |
| | 3 | 163×144 | 95.0 | 28.3 | | | 99.6 | -- |
| | 4 | 164×144 | 95.0 | 28.3 | | | 99.6 | -- |
| | 5 | 165×145 | 95.0 | 28.3 | | | 99.8 | -- |

**Supplementary information:**
1, Each specimen was conditioned at 21 °C and 85 % relative humidity for 4 h to bring them into equilibrium with atmosphere prior to testing.
2, The side of the test specimen was facing towards the challenge aerosol: the inside of the test specimen.

# Surgical mask /
# Surgical mask (Kids) BFE 98%

## CE certificate



| EN 14683:2019+AC:2019 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 5.2.3 | TABLE: Breathability (Differential pressure) | | P |

| Batch/ lot no.: | Test Specimen number-Test area number | Differential pressure for each test area (Pa/cm²) | The averaged differential pressure for each test specimen (Pa/cm²) | Flow rate (l/min) | Remarks |
|---|---|---|---|---|---|
| 20200516 | 1-1 | 26.2 | 26.9 | 8.0 | -- |
| | 1-2 | 28.2 | | 8.0 | -- |
| | 1-3 | 26.9 | | 8.0 | -- |
| | 1-4 | 28.1 | | 8.0 | -- |
| | 1-5 | 25.1 | | 8.0 | -- |
| | 2-1 | 32.0 | 32.2 | 8.0 | -- |
| | 2-2 | 31.9 | | 8.0 | -- |
| | 2-3 | 32.9 | | 8.0 | -- |
| | 2-4 | 31.3 | | 8.0 | -- |
| | 2-5 | 33.1 | | 8.0 | -- |
| | 3-1 | 29.6 | 29.2 | 8.0 | -- |
| | 3-2 | 27.9 | | 8.0 | -- |
| | 3-3 | 30.3 | | 8.0 | -- |
| | 3-4 | 27.6 | | 8.0 | -- |
| | 3-5 | 30.7 | | 8.0 | -- |
| | 4-1 | 31.9 | 32.3 | 8.0 | -- |
| | 4-2 | 33.4 | | 8.0 | -- |
| | 4-3 | 31.8 | | 8.0 | -- |
| | 4-4 | 31.1 | | 8.0 | -- |
| | 4-5 | 33.2 | | 8.0 | -- |
| | 5-1 | 31.8 | 31.8 | 8.0 | -- |
| | 5-2 | 32.3 | | 8.0 | -- |
| | 5-3 | 29.9 | | 8.0 | -- |
| | 5-4 | 33.0 | | 8.0 | -- |
| | 5-5 | 31.9 | | 8.0 | -- |

**Supplementary information:**
Each specimen was conditioned at 21 °C and 85 % relative humidity for 4 h to bring them into equilibrium with

# Surgical mask /
# Surgical mask (Kids) BFE 98%

## CE certificate



| EN 14683:2019+AC:2019 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| atmosphere prior to testing. | | | |
| 5.2.4 | TABLE: Splash resistance | | P |

| Batch/ lot no.: | Test mask no.: | The material of tested mask | Test result (Pass/fail) | Remarks |
|---|---|---|---|---|
| 20200516 | 1 | See clause 5.1.1 | Pass | -- |
| | 2 | | Pass | -- |
| | 3 | | Pass | -- |
| | 4 | | Pass | -- |
| | 5 | | Pass | -- |
| | 6 | | Pass | -- |
| | 7 | | Pass | -- |
| | 8 | | Pass | -- |
| | 9 | | Pass | -- |
| | 10 | | Pass | -- |
| | 11 | | Pass | -- |
| | 12 | | Pass | -- |
| | 13 | | Pass | -- |
| | 14 | | Pass | -- |
| | 15 | | Pass | -- |
| | 16 | | Pass | -- |
| | 17 | | Pass | -- |
| | 18 | | Pass | -- |
| | 19 | | Pass | -- |
| | 20 | | Pass | -- |
| | 21 | | Pass | -- |
| | 22 | | Pass | -- |
| | 23 | | Pass | -- |
| | 24 | | Pass | -- |
| | 25 | | Pass | -- |
| | 26 | | Pass | -- |
| | 27 | | Pass | -- |
| | 28 | | Pass | -- |

# Surgical mask /
# Surgical mask (Kids) BFE 98%

## CE certificate



| EN 14683:2019+AC:2019 | | | | |
|---|---|---|---|---|
| Clause | Requirement + Test | | Result - Remark | Verdict |
| | 29 | | Pass | -- |
| | 30 | | Pass | -- |
| | 31 | | Pass | -- |
| | 32 | | Pass | -- |

**Supplementary information:**

1, Each specimen was conditioned at 21 °C and 85 % relative humidity for 4 h to bring them into equilibrium with atmosphere prior to testing.

2, The description of target area tested: the centre of the specimen.

3, Any technique used to enhance visual detection of synthetic blood: cotton absorbent swab.

4, The temperature and relative humidity for testing: 21 °C and 85 %.

5, Description of any pre-treatment techniques used: N/A.

| 5.2.5 | TABLE: Microbial cleanliness (Bioburden) | | | P |
|---|---|---|---|---|
| **Batch/ lot no.:** | **Mask(under test) no.:** | **Weight of each mask (g)** | **Total bioburden per individual mask (CFU/g)** | **Remarks** |
| 20200516 | 1 | 3.00 | 19 | -- |
| | 2 | 3.01 | 15 | -- |
| | 3 | 3.01 | 25 | -- |
| | 4 | 2.99 | 21 | -- |
| | 5 | 3.00 | 16 | -- |

**Supplementary information:**

**End of EN 14683 test report**

Star Care

# Disposable face mask BFE 98%

## Certificate

# Disposable face mask
# BFE 98%

## Certificate

intertek
Total Quality. Assured.

**TEST REPORT NUMBER:** PRTT00078126 

**APPLICANT:** STARTIC INNOVACION, S.A. **DATE OF EMISSION:** 01/10/2020

CALLE CASTILLA, No. 18

MADRID, SPAIN
28039

**For the attention of Ivan García**

**SAMPLE DESCRIPTION:** Type Mask : Medical Face (Type IIR)
Reference : Star Care Quirúrgica 175*94
1 - Medical Face (Masks)

**DATE OF RECEPTION:** 23/09/2020

**TEST PERFORMED BETWEEN DATES:** 23/09/2020 and 01/10/2020

**WORK DAYS:** 7

**REQUEST:** Tests performed in accordance with APPLICANT TEST REQUEST specification

**NOTES:**

**Samples**

| Test | 1 |
|---|---|
| *‡ BFE (FILTRATION) | M |
| *‡ DIFFERENCIAL PRESSURE (BREATHABILITY) | M |
| *‡ MICROBIAL CLEANLINESS/BIOBURDEN | M |
| *‡ SPLASH RESISTANCE PRESSURE | M |

M = Meet buyer's requirement; NM = does not meet buyer's requirement; NR = Not requested; NA = Not applicable; NC = No comment; SC = Still continues
- Test results relate only to submitted items. The report shall not be reproduced except in full, without the written approval of Intertek Portugal.
- Tests marked by (*) are not included in the scope of IPAC accreditation for this Laboratory.
- Tests marked by (*‡) have been sub-contracted by this Laboratory, are not included in the scope of IPAC accreditation.
Consult our terms and conditions on http://www.intertek.pt/termos-e-condicoes/.

Textiles Laboratory Manager
ana.morgado@intertek.com

# Disposable face mask
# BFE 98%

## Certificate

intertek
Total Quality. Assured.



| Test Method | Results | Requirements |
|---|---|---|

***‡ BFE (FILTRATION)**

EN 14683:2019+AC 2019

Sample: 1

Type IIR >/= 98%

RESULT

98.5%

Test Conditions:

Temperature: 21±5ºC Humidity: 85±5%

Dimensions of the test specimens: 49cm2 (5 test specimens)

Side of the test specimen facing the challenge aerossol: intern

Air flow rate: 28.3 l/min.

MPS 2.9

Test specimen 1 (98.7%), Test specimen 2 (98.2%), Test specimen 3 (98.0%), Test specimen 4 (98.7%), Test specimen 5 (98.8%).

The expanded uncertainty at a confidence level of 95%, k=2: 1.8%

***‡ DIFFERENCIAL PRESSURE (BREATHABILITY)**

EN 14683:2019+AC 2019

Sample: 1

Type IIR <60 Pa/cm2

RESULT

32.4 Pa/cm2

Test Conditions:

Temperature: 21±5ºC Humidity: 85±5%

Number and general location of the areas of the mask the differential measurements were taken: Test performed with the direction of flow from the inside to the outside. Side and central location.

Air flow rate: 8L/min

Dimensions of the test specimens: 4.9cm2 (5 test specimens)

Test specimen 1 (33.7 Pa/cm2), Test specimen 2 (32.7 Pa/cm2), Test specimen 3 (32.7 Pa/cm2), Test specimen 4 (31.6 Pa/cm2), Test specimen 5 (31.6 Pa/cm2)

The expanded uncertainty at a confidence level of 95%, k=2: 8.7%

# Disposable face mask
# BFE 98%

## Certificate

intertek
Total Quality. Assured.

**TEST REPORT NUMBER:** PRTT00078126 

***‡ MICROBIAL CLEANLINESS/BIOBURDEN**

EN ISO 11737-1:2018

Sample: 1 Type IIR </= 30 cfu/g

RESULT

11 UFC/g

Test Conditions:
5 min shaker at 250rpm
Área of each test specimen: 5 test specimens
Mic30ºC (3 days), Molds and yeasts 25ºC (7 days)

Results: 24, 2, 18, 4, 4

The expanded uncertainty at a confidence level of 95%, k=2: 20%

***‡ SPLASH RESISTANCE PRESSURE**

ISO 22609:2004

Sample: 1 Type IIR >/= 16.0 kPa

RESULT

16 kPa

Test conditions: Samples pre-condictioned for at least 4 hoursat Temperature and Relative humidity: 21±5ºC / 85± 5 %
Samples exposed to a jet of 2mL synthetic blood at pressure (low: 10.6 KPa; medium: 16.0 KPa; high:21.3 KPa) aimed at the centre of the mask.
Test performed at laboratory temperature of 21ºC and 45% relative humidity, within 60 seconds after the mask was removed from the conditioning chamber
Observation after 10+1 second of blood penetration on the opposite side of the mask.
Synthetic blood according to Annex B of ISO 22609: 2004 with surface tension of 42 + 2mN / m, batch # 202010
Number and General location of the áreas: 32 test specimen / center (pass at least Medium pressure test for 29 out of 32 samples as minimum, corresponding to AQL 4%, acording EN 14683: 2019 mask Type IIR)
Results:
Médium pressure (16.0KPa) 32 specimen "pass", 0 specimen "fail"

# Disposable face mask
# BFE 98%

## Certificate

intertek
Total Quality. Assured.

**TEST REPORT NUMBER:** PRTT00078126 

Sample: 1 Type IIR >/= 16.0 kPa

RESULT

Medium pressure test for 29 out of 32 samples as minimum, corresponding to AQL 4%, acording EN 14683: 2019 mask Type IIR)

| Sample | Medium Pressure 16.0 Kpa |
|---|---|
| Amost1 | Pass |
| Amost2 | Pass |
| Amost3 | Pass |
| Amost4 | Pass |
| Amost5 | Pass |
| Amost6 | Pass |
| Amost7 | Pass |
| Amost8 | Pass |
| Amost9 | Pass |
| Amost10 | Pass |
| Amost11 | Pass |
| Amost12 | Pass |
| Amost13 | Pass |
| Amost14 | Pass |
| Amost15 | Pass |
| Amost16 | Pass |
| Amost17 | Pass |
| Amost18 | Pass |
| Amost19 | Pass |
| Amost20 | Pass |
| Amost21 | Pass |
| Amost22 | Pass |
| Amost23 | Pass |
| Amost24 | Pass |
| Amost25 | Pass |
| Amost26 | Pass |
| Amost27 | Pass |
| Amost28 | Pass |
| Amost29 | Pass |

# Disposable face mask
# BFE 98%

Certificate

intertek
Total Quality. Assured.

**TEST REPORT NUMBER:** PRTT00078126 

Sample: 1 Type IIR >/= 16.0 kPa

RESULT

| | |
|---|---|
| Amost30 | Pass |
| Amost31 | Pass |
| Amost32 | Pass |

# Disposable face mask
# BFE 98%

Certificate

intertek
Total Quality. Assured.



Star Care

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