
Star Care

Star Care

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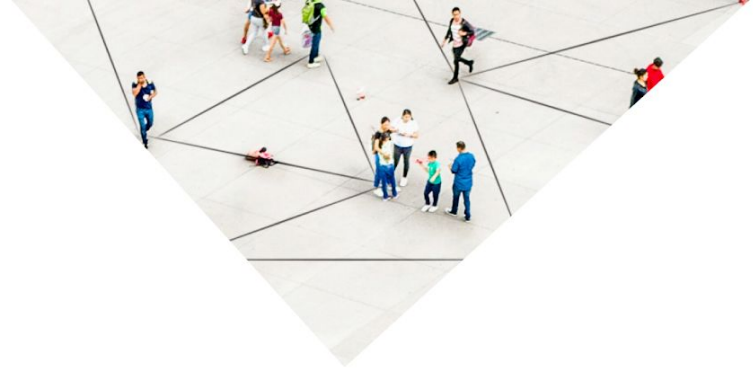

We are
Star Care

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.

Star Care

Star Care

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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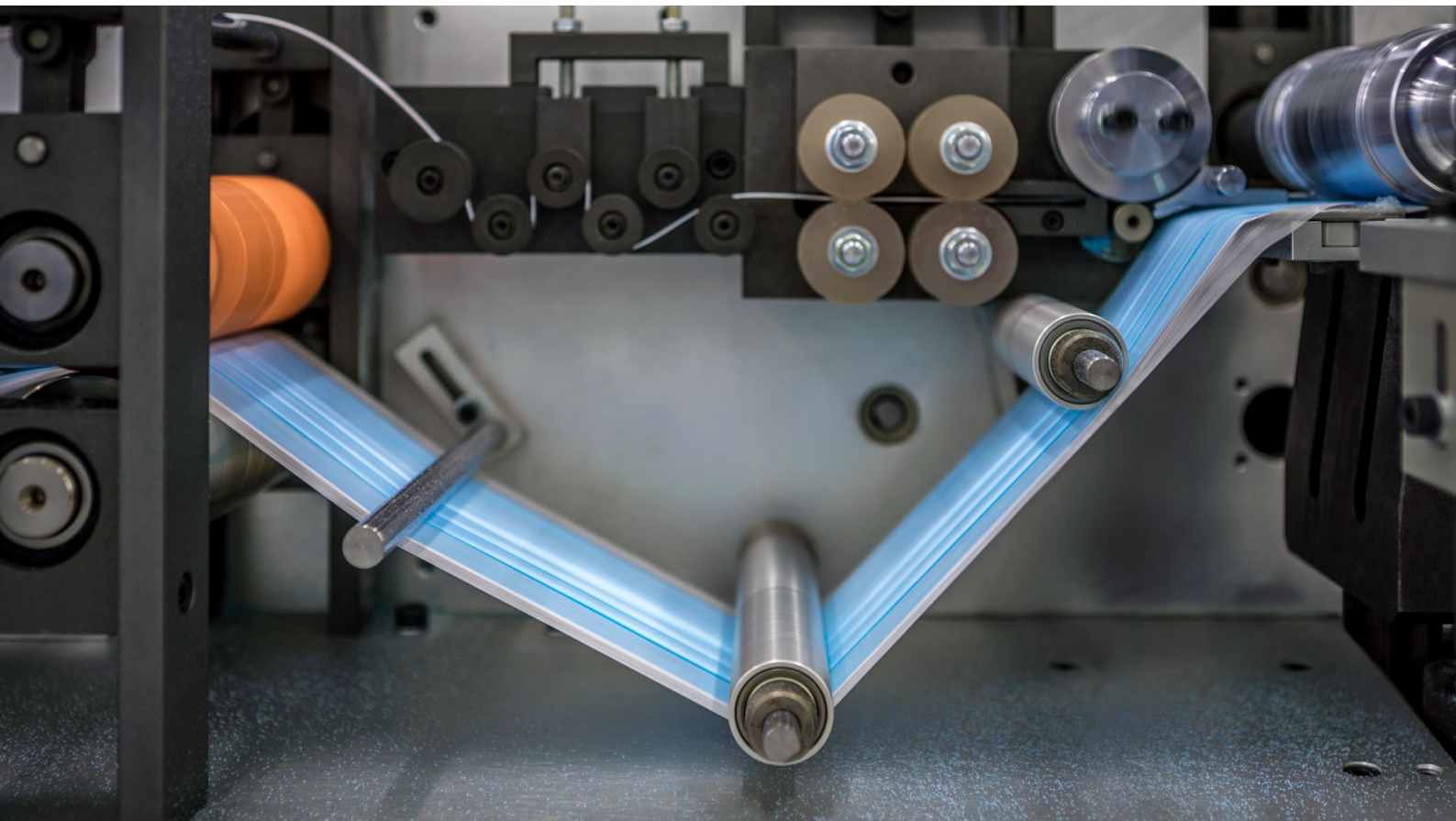
1. Supplier qualification

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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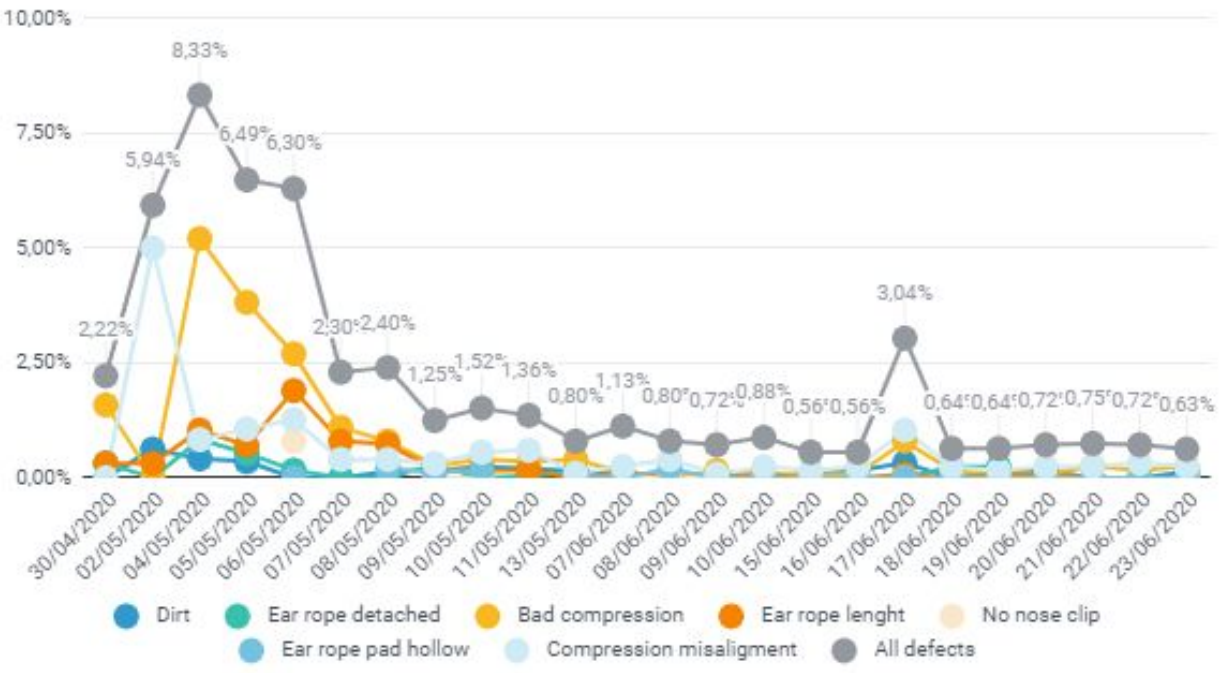
4. Continuous improvement

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

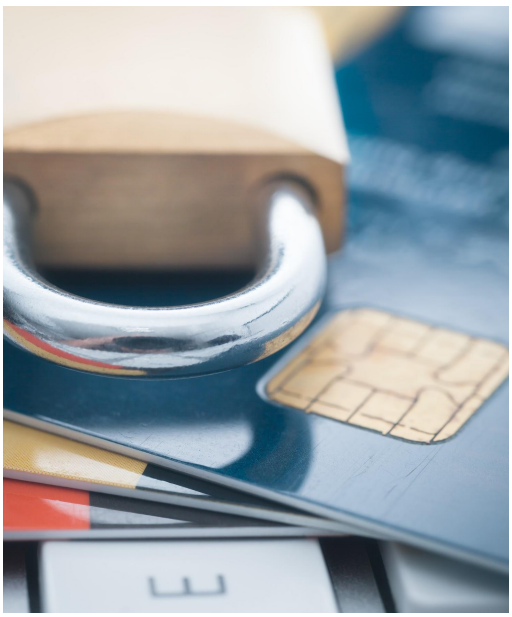
We offer three logistical options:

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.



Star Care

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**

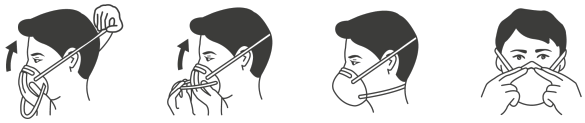
Ear saver included

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

Size XS

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. Size XS

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**

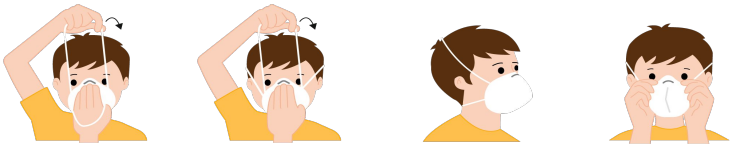
Ear saver included

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

Size XS

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

Star Care

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

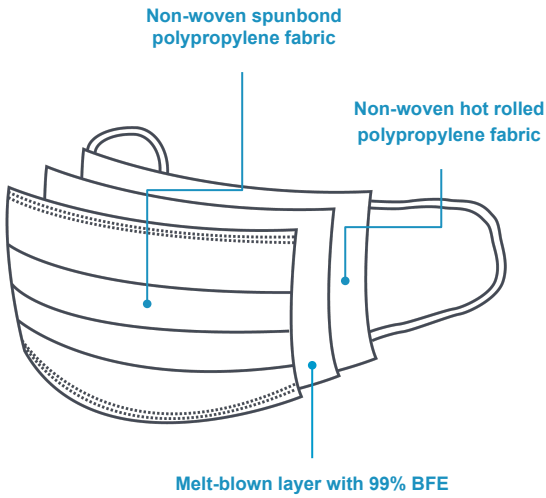
Bacterial filtration efficiency: ≥ 98%

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.

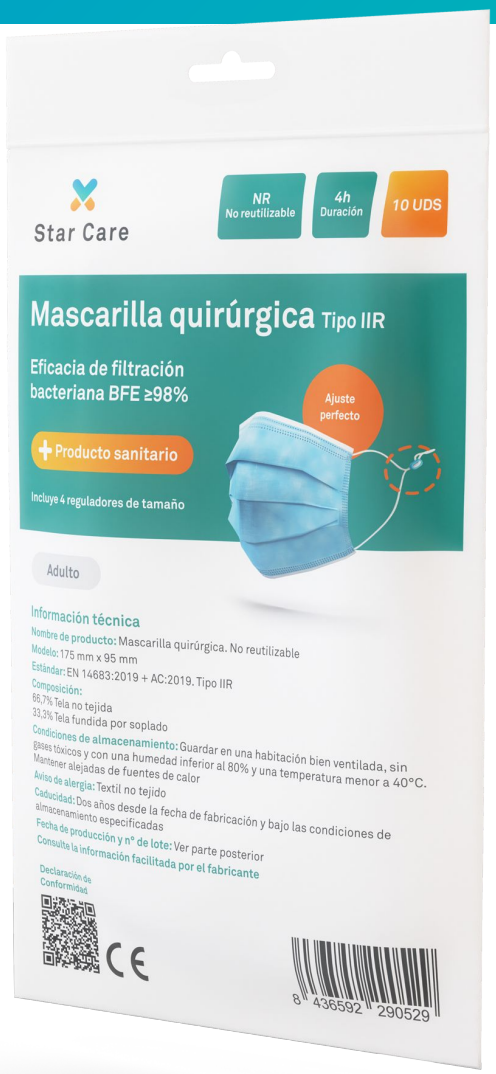
Important information

- 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

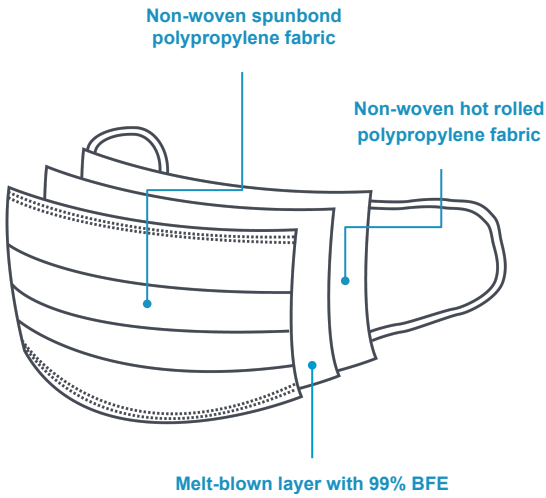
CE

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

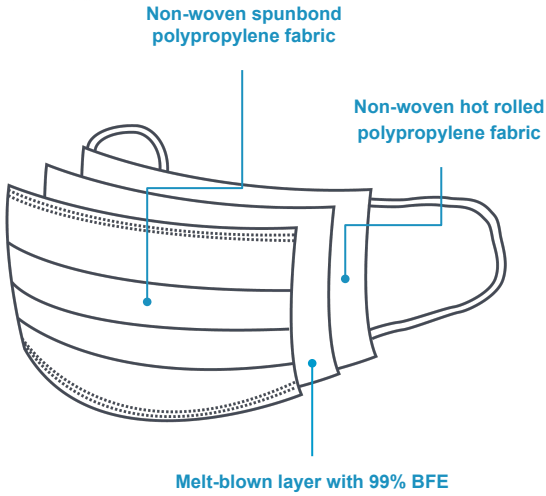
Star Care

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.

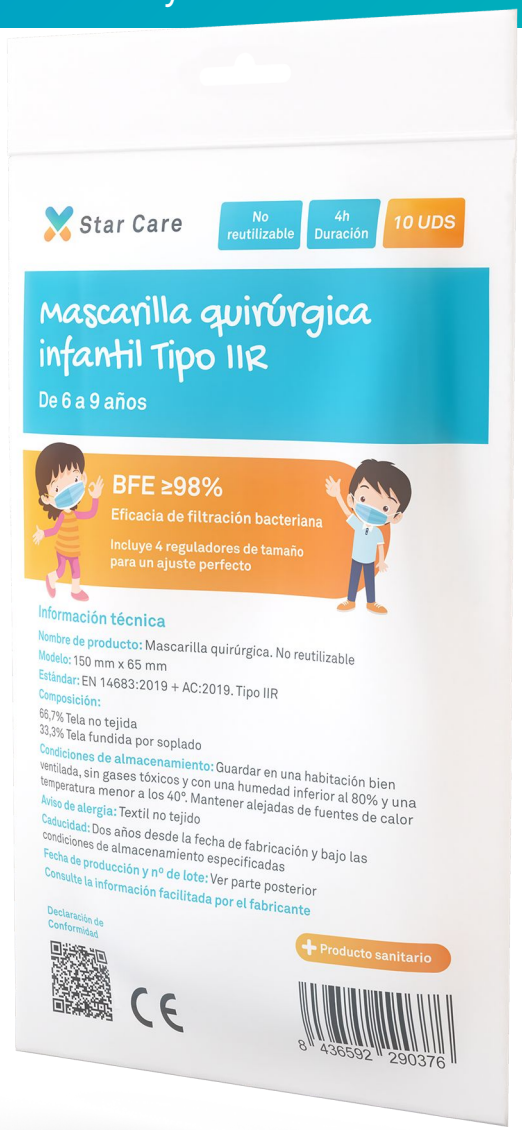
Important information

- 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

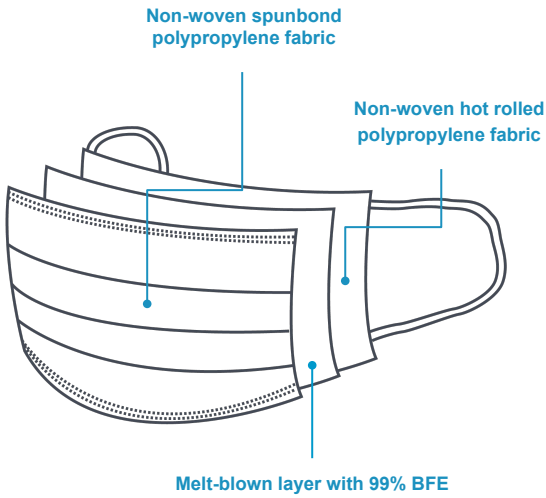
CE

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

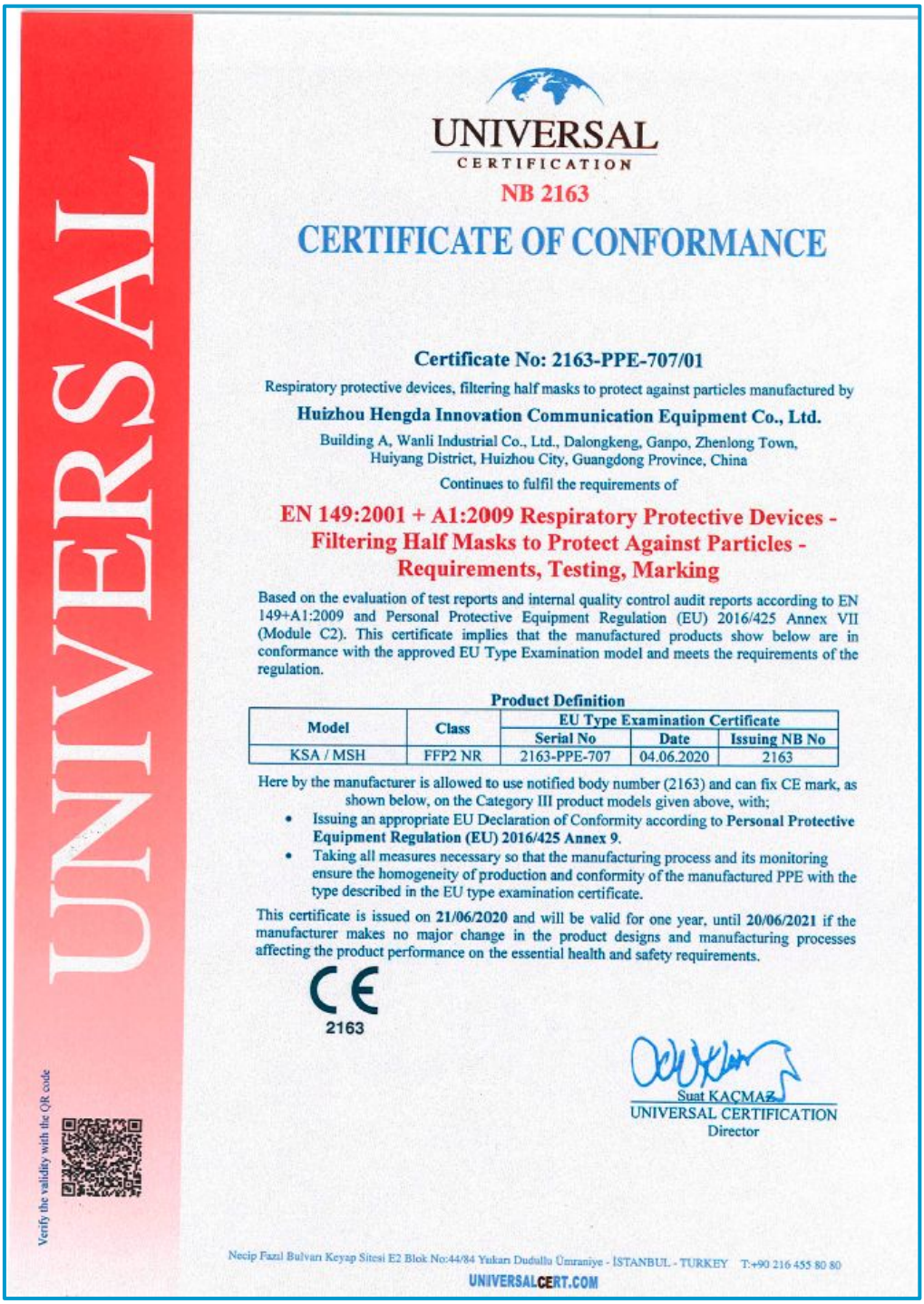
Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye - İSTANBUL - TURKEY T:+90 216 455 80 80

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
Size XS

Certificate

FFP2 mask
Size XS

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)

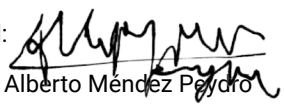
Campus UAB – Ronda de la Font del Carme, s/n

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
Size XS

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

Notified Body No. 0370

CERTIFICADO DE EXAMEN UE DE TIPO
EU-TYPE EXAMINATION CERTIFICATE

ENAC CERTIFICACIÓN Nº 12/C-PR054

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
Size XS

CE certificate

Star Care

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

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 *BRAND*	Star Care
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
INFORME DE ENSAYO *TEST REPORT*	S20102603601E issued by Shenzhen NTEK Testing Technology Co., Ltd. （NTEK）

Star Care

FFP3 masks

Certificate

FFP3 mask

Star Care

Declaration of Conformity

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

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:

0370-5003-PPE/B (Dated 04/01/2021)

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)

Signed for and on behalf of:

Signed:

Name: Alberto Méndez Pedro

Position: President

Place and date: 05/01/2021

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

Notified Body No. 0370

CERTIFICADO DE EXAMEN UE DE TIPO

No. 0370-5003-PPE/B

ORGANISMO NOTIFICADO Nº	**0370 - LGAI TECHNOLOGICAL CENTER** (APPLUS)
SOLICITANTE / FABRICANTE	**Star TIC Innovación, S.A.** C/ Estrasburgo, 8, 28232 Las Rozas de Madrid, España
PLANTA DE PRODUCCIÓN	**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: **REGLAMENTO (UE) 2016/425 SOBRE LOS EQUIPOS DE PROTECCIÓN INDIVIDUAL**	
PROCEDIMIENTO DE EVALUACIÓN DE LA CONFORMIDAD	Módulo: **B** **EXAMEN UE DE TIPO**
IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO)	Ref.: MSH Mascarilla filtrante
NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI	FFP3 NR
NORMAS ARMONIZADAS	EN 149:2001 + A1:2009 Dispositivos de protección respiratoria. Medias máscaras filtrantes de protección contra partículas. Requisitos, ensayos, marcado.
FECHA DE EMISIÓN	**04/01/2021**
VALIDEZ HASTA	**04/01/2026**

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).

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.

Puede comprobarse la validez de este certificado en nuestra página web: *www.appluslaboratories.com/certified_products*

ENAC
CERTIFICACIÓN

FFP3 mask

Star Care

CE certificate

LGAI Technological Center, S.A. (APPLUS)
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08193 Bellaterra (Barcelona)
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Technical Annex Ed. 1
04/01/2021

ANEXO TÉCNICO

0370-5003-PPE/B

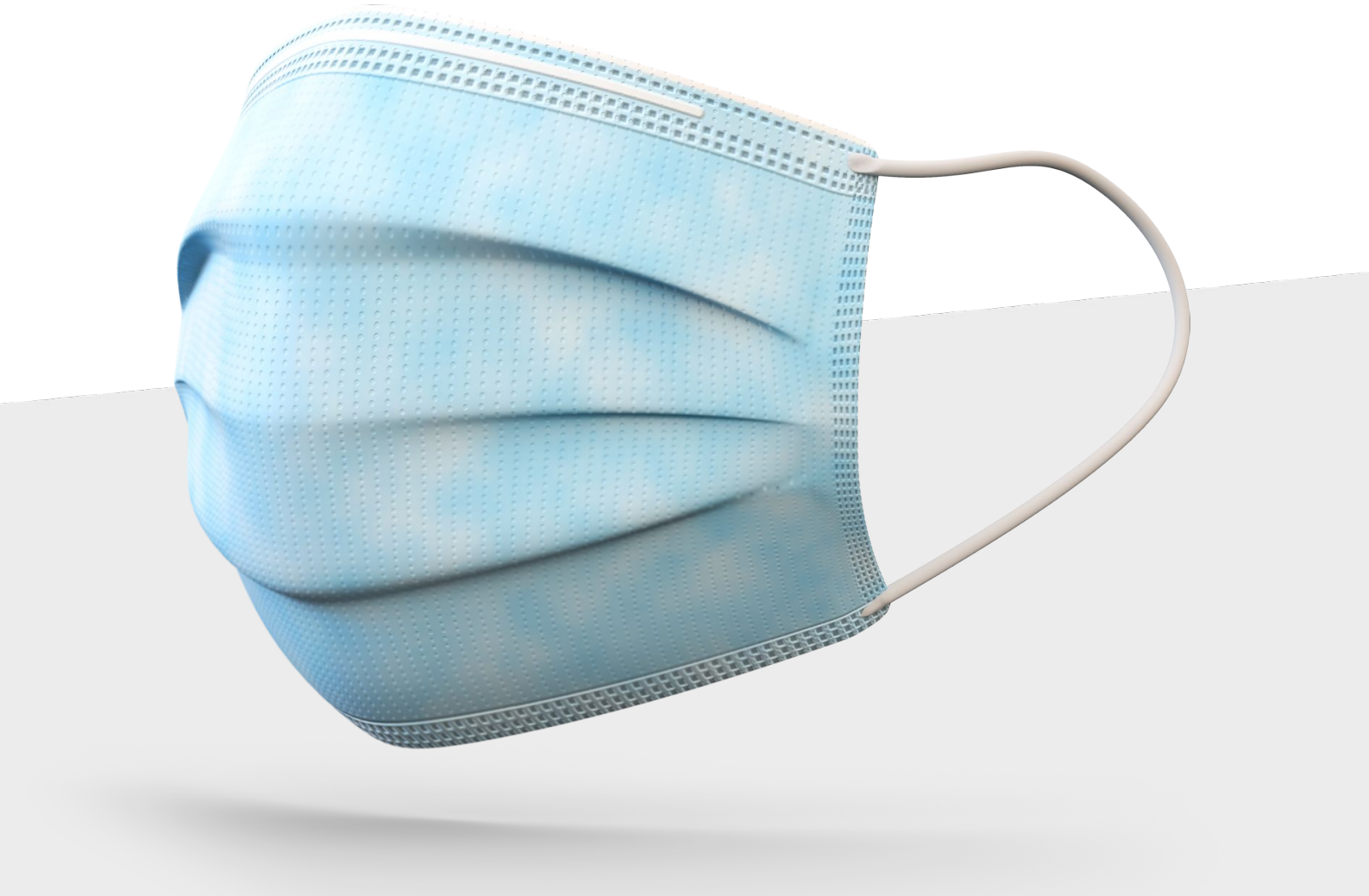
I. MODELOS INCLUIDOS EN EL CERTIFICADO

MARCA	Star Care
IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO)	Ref.: MSH Mascarilla filtrante
NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI	FFP3 NR
INFORME DE ENSAYO	S20112300302E issued by Shenzhen NTEK Testing Technology Co., Ltd. (NTEK)

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 Medical face masks — 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): Construction check according to: Clause 5.1.1 Materials and construction Clause 5.1.2 Design	**Testing location:** **TÜV Rheinland (Shenzhen) Co., Ltd.** 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) Clause 5.2.3 Breathability Clause 5.2.4 Splash resistance Clause 5.2.5 Microbial cleanliness (Bioburden)	**Pony Testing Group Shanghai Co., Ltd.** 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. 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

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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

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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

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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.

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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

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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.
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Textiles Laboratory Manager
ana.morgado@intertek.com

Disposable face mask
BFE 98%

Certificate

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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

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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

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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%

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TEST REPORT NUMBER: PRTT00078126

Sample: 1 Type IIR >/= 16.0 kPa

RESULT

Amost30	Pass
Amost31	Pass
Amost32	Pass

Disposable face mask
BFE 98%

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