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1. ¿Quiénes somos?

2. Material de protección

a. Mascarilla FFP2
b. Mascarilla quirúrgica Tipo IIR
c. Mascarilla higiénica BFE > 98%
d. Mascarilla higiénica niños BFE > 98%
e. Gel Hidroalcohólico

3. Certificados

a. Mascarilla FFP2
   - Declaración de Conformidad
   - Certificado CE

b. Mascarillas quirúrgica / higiénica
   - Declaración de conformidad
   - Certificado CE
   - Physical & Microbiological Test
   - Biocompatibility Test

Somos
Star Care

Star Care es la línea de cuidado y prevención del holding europeo Star TIC Innovación.

Los productos Star Care cumplen todos los estándares oficiales y están testados y probados por empresas de certificación europeas, frente a otros productos que vienen directamente de países asiáticos bajo certificados falsos y sin control alguno.

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Somos un fabricante **fiable y seguro**

¿Cómo trabajamos?

Control y seguridad en toda la cadena de producción:

1. Elección de partners
2. Inspecciones durante la producción (IPQC)
3. Inspecciones al producto final (OQC)
4. Control de trazabilidad
5. Auditoría externa
6. Pruebas de fiabilidad adicionales

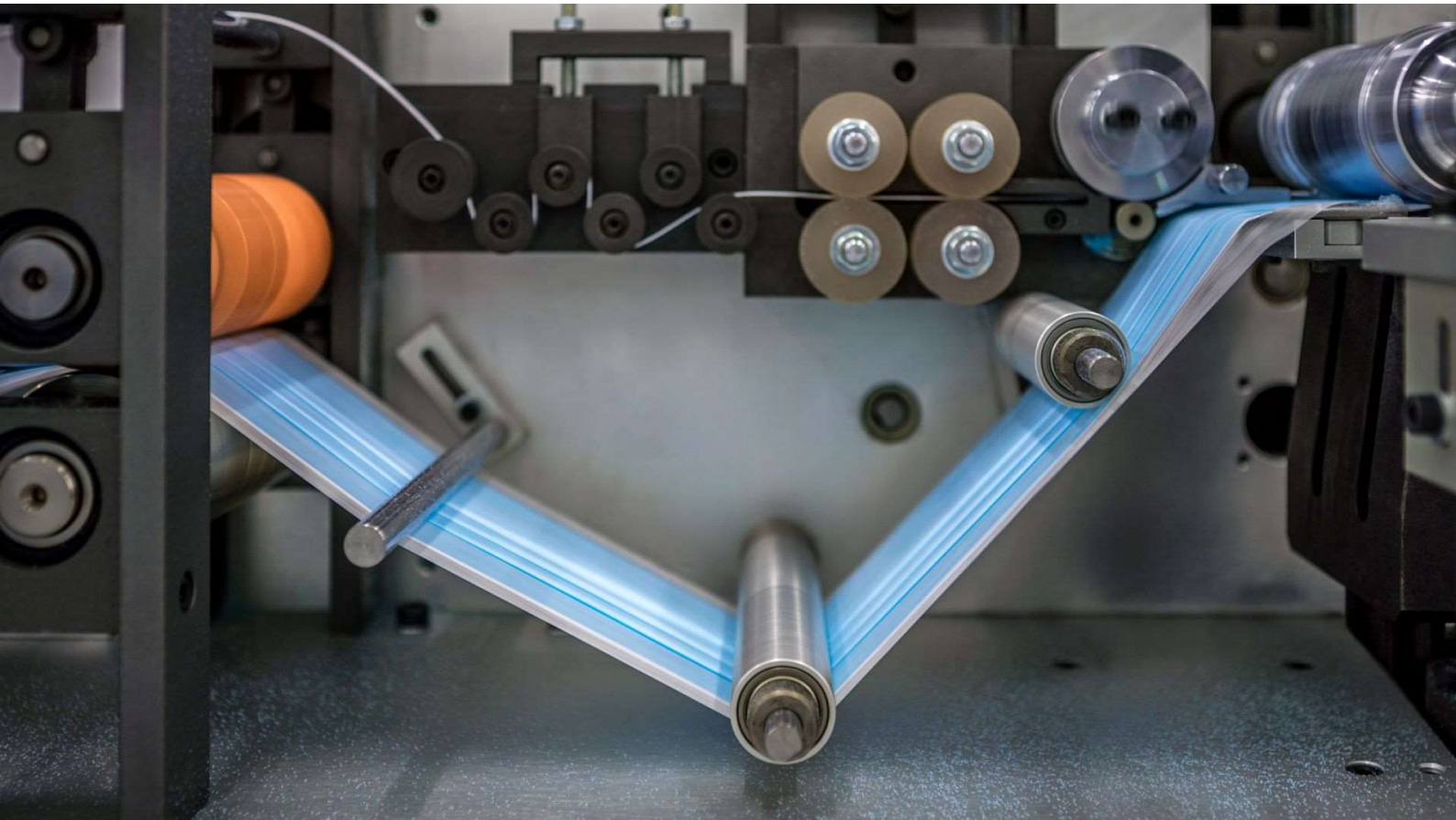
Star Care

1. Cualificación de proveedores

Todos los suppliers implicados en la fabricación de nuestros productos cumplen **estrictos requisitos de calidad**.

Nuestro proceso de selección:

1. **Elección provisional** en base a criterios estratégicos y **contacto inicial**.
2. **Auditoría:** comprobación in situ de las instalaciones y de sus conocimientos técnicos, de proceso y de gestión de calidad.
3. **Investigación del background:** análisis de su posición financiera para garantizar su solvencia y la seguridad de potenciales acuerdos entre ambos.
4. **Registro y puntuación:** registro de toda la información en nuestra base de datos para seleccionarlo como supplier en aquellos proyectos en los que sea la opción más adecuada.



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2. Inspecciones durante la producción (IPQC)

Durante la fabricación, realizamos intensivas inspecciones para asegurarnos de que se **cumplen los objetivos mínimos establecidos**.
Estas pruebas son **independientes y adicionales** a las que hace el propio supplier y están adaptadas al tipo de producto. Entre ellas destacan:

- **Test de filtración**
- **Test de respirabilidad**
- **Controles higiénicos en la producción**
- **Adecuada indumentaria, equipación y formación de los operarios**
- **Precisión en la carga de material al proceso**

Uno de los mejores ejemplos de **rigurosidad en el control de calidad** es el del **meltblown**, el principal material de la mascarilla. Hacemos controles preventivos para detectar cambios en su origen, tejido o filtración a la entrada del material en la maquinaria y en el producto.

3. Inspecciones al producto final (OQC)

Aplicamos el estándar **AQL (Límite de Calidad Aceptable)** y realizamos una batería de test sobre una parte de la producción seleccionada aleatoriamente.

Niveles de aceptabilidad

Nuestros **niveles de aceptabilidad son los más estrictos de la industria**. Nuestro máximo es 0.65 para defectos *major,* 1.5 para *minor* y no aceptamos defectos *critical*.

Muestra

En los controles de calidad de nuestros modelos, el tamaño de la muestra viene determinado por **el nivel de inspección III, el más exigente que existe**. Como se puede apreciar en la tabla, establece la muestra más grande que se puede obtener para asegurar la mayor precisión.

Registro y control

Registramos el resultado de cada lote para un posterior análisis y trazabilidad. Este seguimiento nos permite elaborar y ejecutar planes de mejora continua y monitorizar la calidad del proveedor.

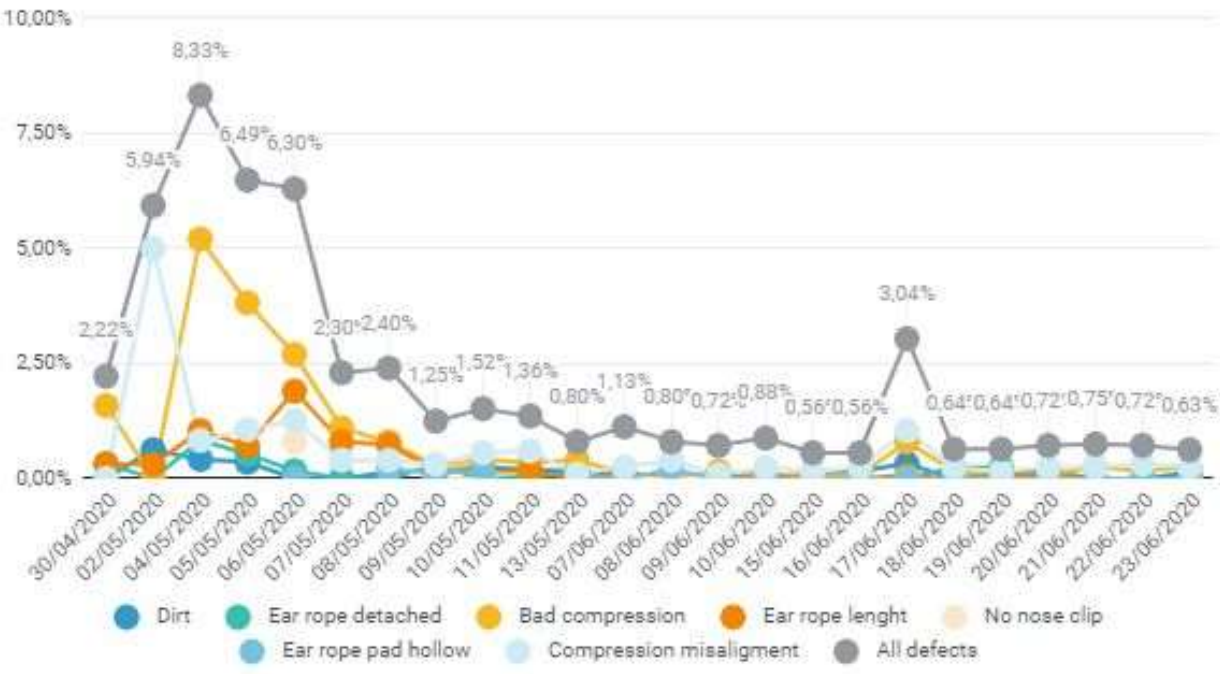
Star Care

4. Mejora continua

Con cada resultado de las inspecciones durante la producción, **trabajamos con el proveedor en un plan de acción** para cada punto de mejora. Nos aseguramos de que lo lleva a cabo en las siguientes producciones y **comprobamos que estas acciones mejoran la calidad** de la fabricación.

Planificación y ejecución de las inspecciones	Análisis de resultados y toma de medidas	Consolidación y comprobación de los resultados

Este gráfico de uno de nuestros proveedores muestra cómo, tras implantar nuestro plan de mejora el 7 de mayo, comenzó a experimentar un descenso generalizado en el porcentaje de defectos.



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5. Control de trazabilidad y gestión de cambios

Conocemos la configuración de la producción y almacenamos toda la información que permite **rastrear cualquier potencial incidencia**. Además, controlamos cualquier cambio realizado en la configuración de la fabricación o el producto (ECR) para poder identificar a qué lotes afectaría o desde cuando.

Star Care

6. Inspección externa

Nuestros productos pasan un segundo control de calidad con empresas de certificación occidentales como Bureau Veritas y SGS. Además, sometemos periódicamente nuestros criterios a su auditoría e inspección para actualizarlos continuamente.

7. Pruebas en laboratorios

Nuestros productos pasan el control externo de los laboratorios líderes del sector de China y España. Allí se verifica que **cumplen los requisitos mínimos exigidos**, como test de filtración, test de respirabilidad o materiales empleados.

Máquina de test de filtración FPE

Star Care

Entrega garantizada

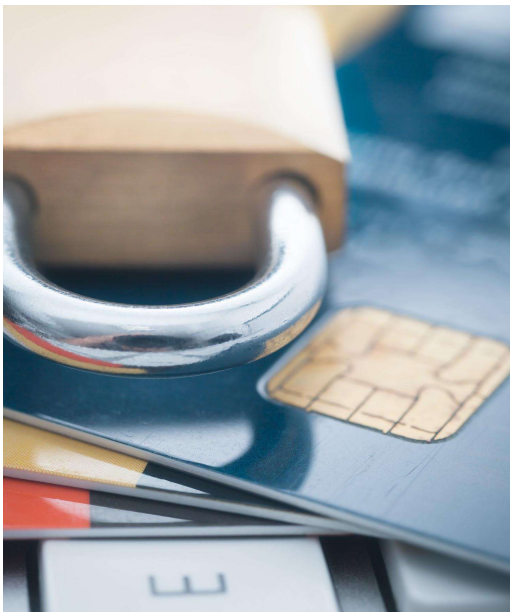
Ofrecemos tres opciones logísticas:

1. **Delivered Duty Paid** (DDP): entrega de la mercancía lista para su descarga con los trámites aduaneros de importación realizados.
2. **Delivered at Place Unloaded** (DPU): suministro en el lugar de descarga establecido (puerto o terminal).
3. **Free Carrier** (FCA): entrega al transportista o persona de tu elección en Shenzhen o Cantón y carga en tu medio de transporte.

Seguridad financiera

Para tu tranquilidad, aceptamos **cartas de crédito documentadas** (solo se harán efectivas tras aportar la documentación y certificación de las mascarillas) y **pago por transferencia bancaria**.

Monedas aceptadas: AUD, CAD, CHF, EUR, GBP, HKD, JPY, NZD, SGD, USD, CNH, DKK, NOK y SEK.



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Material de protección

Mascarilla FFP2
Ajuste en oreja

Star Care

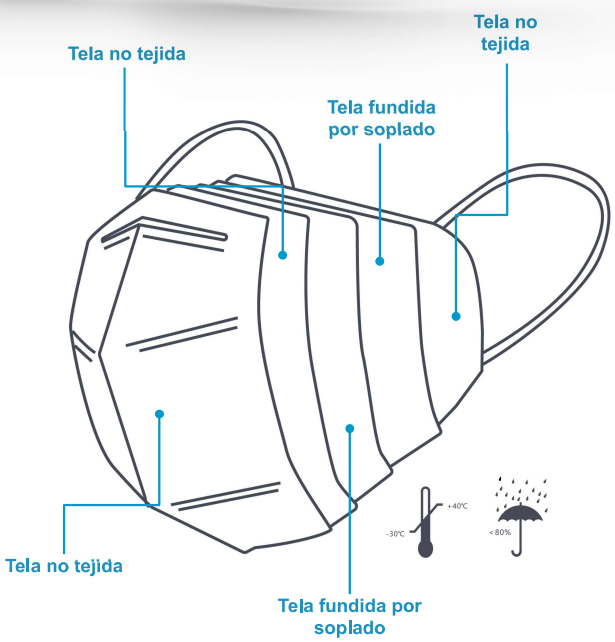
FFP2

Mascarilla filtrante

> 98 filtración de aerosoles de partículas

Información técnica

Nombre de producto: Mascarilla de filtración
Clasificación: FFP2 - NR (No reutilizable)
Modelo: MSH
BFE > 98 %
PFE > 94 % (>98% para aerosoles de NaCl)
Tamaño: 15,7 x 10,7 cm
Estándar: EN 149:2001 + A1:2009
Composición: 66,7% Tela no tejida, 33,3% tela fundida por soplado
Aviso de alergia: Textil no tejido
Caducidad: Dos años bajo las condiciones de almacenamiento especificadas
Accesorios: Salvaorejas, reguladores de tamaño



EPI

Instrucciones para ponerse la mascarilla

1. Sujétela con una mano, con el clip nasal orientado hacia los dedos y las cintas de sujeción colgando.
2. Coloque la mascarilla sobre la cara cubriendo totalmente la nariz y la boca. El clip nasal debe quedar sobre la nariz.
3. Sujete la mascarilla con una mano sobre la barbilla. Tire de la cinta y colóquela detrás de la oreja.
4. Ajuste el clip nasal a la nariz con ambas manos y asegúrese de que los bordes de la mascarilla están en contacto directo con la cara.
5. Haga una prueba de ajuste-fuga para comprobar que se ha puesto la mascarilla de forma correcta. Cubra la mascarilla con las dos manos y exhale con fuerza. Si detecta fugas a través de los bordes, modifique la posición de la mascarilla sobre la cara, reajuste el clip nasal o ajuste la tensión de las cintas de sujeción. Repita este proceso hasta que no detecte ninguna fuga.

CE 2163

EN 149:2001 + A1:2009

Mascarilla FFP2
Ajuste en oreja

Star Care

FFP2

Mascarilla filtrante

> 98 filtración de aerosoles de partículas

Información importante

- Los equipos NR no deben usarse en más de 8 horas.
- Usar bajo las recomendaciones del fabricante, siguiendo las instrucciones del etiquetado.
- Estas mascarillas no aportan oxígeno.
- No usar en atmósferas con baja concentración de oxígeno o zonas poco ventiladas.
- La presencia de características faciales especiales, vello abundante o gafas puede impedir un correcto ajuste de la mascarilla.
- Mantener alejadas de fuentes de calor.
- Guardar en un espacio interior bien ventilado, con humedad inferior al 80% y sin gases corrosivos.

Características de la bolsa individual

Cantidad: 1 ud/bolsa
Dimensión: 205 x 130 mm
Peso: 12 g

SKU: MASK-ST-00029.0001

8 436592 290444

SKU: MASK-ST-00013.0001

8 436592 290116

Características del paquete 10 uds

Cantidad: 10 uds(bolsas individuales)/paquete
Dimensión: 210 x 195 x 131,2 mm
Peso: 130 g

SKU: MASK-ST-00029.0001

8 436592 290512

SKU: MASK-ST-00009.0010

8 436592 290314

Características de la caja

Cantidad: 60 paquetes/caja
Total cantidad: 600 unidades
Dimensión: 620*545*234 mm
Peso: 8,5 kg

CE 2163

EN 149:2001 + A1:2009

Mascarilla FFP2
Ajuste en nuca

Star Care

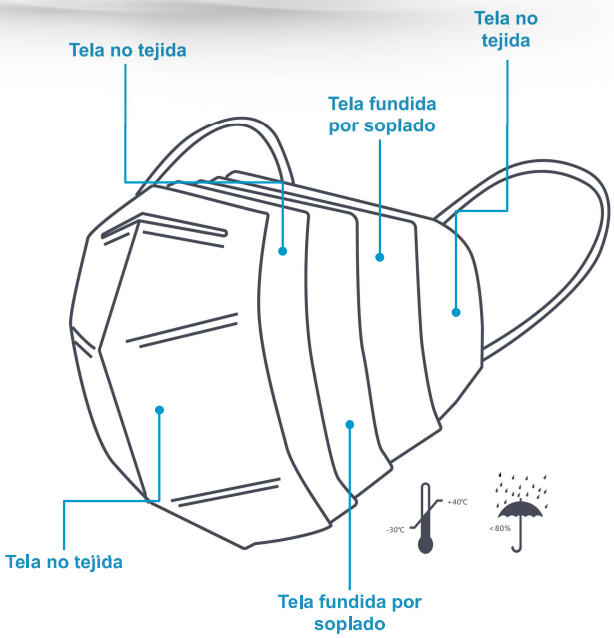
FFP2

Mascarilla filtrante

> 98 filtración de aerosoles de partículas

Información técnica

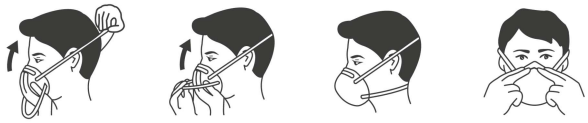
Nombre de producto: Mascarilla de filtración
Clasificación: FFP2 - NR (No reutilizable)
Modelo: MSH
BFE > 98 %
PFE > 94 % (>98% para aerosoles de NaCl)
Tamaño: 15,7 x 10,7 cm
Estándar: EN 149:2001 + A1:2009
Composición: 66,7% Tela no tejida, 33,3% tela fundida por soplado
Aviso de alergia: Textil no tejido
Caducidad: Dos años bajo las condiciones de almacenamiento especificadas
Accesorios: Regulador de tamaño incluido



EPI

Instrucciones para ponerse la mascarilla

1. Sujete la mascarilla con una mano, posicionándola en la cara de forma que cubra la nariz y la barbilla.
2. Coloque la cinta superior por detrás de la cabeza.
3. A continuación, pase la cinta inferior por detrás de la cabeza hasta colocarla a la altura de la nuca. Ajuste el regulador para una sujeción óptima.
4. Ajuste el clip nasal a la nariz con ambas manos y asegúrese de que los bordes de la mascarilla están en contacto directo con la cara.
5. Haga una prueba de ajuste-fuga para comprobar que se ha puesto la mascarilla de forma correcta. Cubra la mascarilla con las dos manos y exhale con fuerza. Si detecta fugas a través de los bordes, modifique la posición de la mascarilla sobre la cara, reajuste el clip nasal o ajuste la tensión de las cintas de sujeción. Repita este proceso hasta que no detecte ninguna fuga.



CE 2163

EN 149:2001 + A1:2009

Mascarilla FFP2
Ajuste en nuca

Star Care

FFP2

Mascarilla filtrante

Mascarilla de protección 94% filtración para la contaminación de partículas

Información importante

- Los equipos NR no deben usarse en más de un turno de trabajo.
- Usar bajo las recomendaciones del fabricante, siguiendo las instrucciones del etiquetado.
- Estas mascarillas no aportan oxígeno.
- No usar en atmósferas con baja concentración de oxígeno o zonas poco ventiladas.
- La presencia de características faciales especiales, vello abundante o gafas puede impedir un correcto ajuste de la mascarilla.
- Mantener alejadas de fuentes de calor.
- Guardar en un espacio interior bien ventilado, con humedad inferior al 80% y sin gases corrosivos.

Características de la bolsa individual

Cantidad: 1 ud/bolsa
Dimensión: 205 x 130 mm
Peso: 12 g

SKU: MASK-ST-00033.0001

8 436592 290635

SKU: MASK-ST-00019.0001

8 436592 290208

Características del paquete 10 uds

Cantidad: 10 uds(bolsas individuales)/paquete
Dimensión: 210 x 195 x 131,2 mm
Peso: 135 g

SKU: MASK-ST-00033.0010

8 436592 290642

SKU: MASK-ST-00019.00010

8 436592 290628

Características de la caja

Cantidad: 60 paquetes/caja
Total cantidad: 600 unidades
Dimensión: 620*545*234 mm
Peso: 8,5 Kg

CE 2163

EN 149:2001 + A1:2009

Mascarilla FFP2
Infantil. 6 - 12 años

Star Care

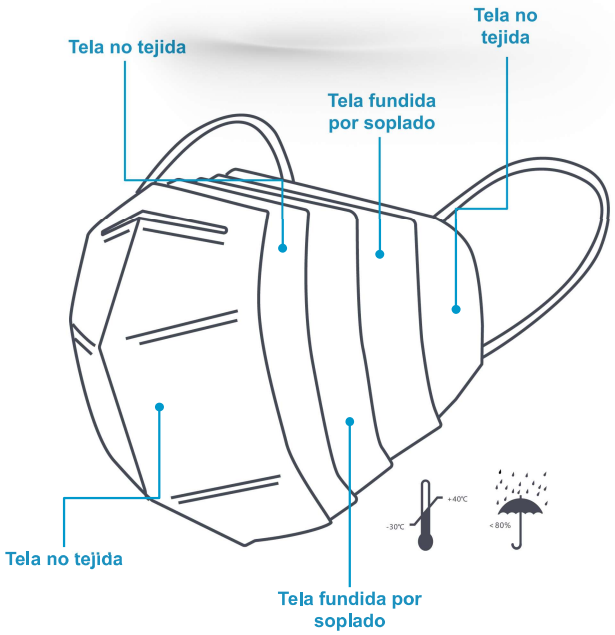
FFP2

Mascarilla de filtración

Infantil. De 6 a 12 años

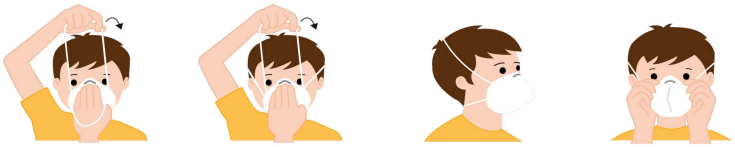
Información técnica

Nombre de producto: Mascarilla de filtración
Clasificación: FFP2 - NR (No reutilizable)
Modelo: STC-FP-01
Tamaño: 113 x 95 mm
Edad recomendada: 6 - 12 años
Estándar: EN 149:2001 + A1:2009
Composición: 66,7% Tela no tejida, 33,3% tela fundida por soplado
Aviso de alergia: Textil no tejido
Caducidad: Dos años bajo las condiciones de almacenamiento especificadas
Accesorios: Regulador de tamaño incluido



Instrucciones para ponerse la mascarilla

1. Sujétela con una mano, con el clip nasal orientado hacia los dedos y las cintas de sujeción colgando.
2. Coloque la mascarilla sobre la cara cubriendo totalmente la nariz y la boca. El clip nasal debe quedar sobre la nariz.
3. Sujete la mascarilla con una mano sobre la barbilla. Tire de la cinta y colóquela detrás de la oreja.
4. Ajuste el clip nasal a la nariz con ambas manos y asegúrese de que los bordes de la mascarilla están en contacto directo con la cara.
5. Haga una prueba de ajuste-fuga para comprobar que se ha puesto la mascarilla de forma correcta. Cubra la mascarilla con las dos manos y exhale con fuerza. Si detecta fugas a través de los bordes, modifique la posición de la mascarilla sobre la cara, reajuste el clip nasal o ajuste la tensión de las cintas de sujeción. Repita este proceso hasta que no detecte ninguna fuga.



CE 2163

EN 149:2001 + A1:2009

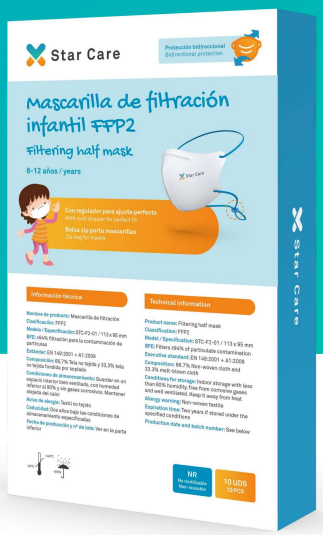
Mascarilla FFP2
Infantil. 6 - 12 años

Star Care

FFP2

Mascarilla de filtración

Infantil. De 6 a 12 años



Información importante

- Los equipos NR no deben usarse más de 8 horas.
- Usar bajo las recomendaciones del fabricante, siguiendo las instrucciones del etiquetado.
- Estas mascarillas no aportan oxígeno.
- No usar en atmósferas con baja concentración de oxígeno o zonas poco ventiladas.
- La presencia de características faciales especiales, vello abundante o gafas puede impedir un correcto ajuste de la mascarilla.
- Mantener alejadas de fuentes de calor.
- Guardar en un espacio interior bien ventilado, con humedad inferior al 80% y sin gases corrosivos.

Características de la bolsa individual

Cantidad: 1 ud/bolsa
SKU: MASK-ST-00031.0001
Dimensión: 185 x 130 mm
Peso:12 g

8 436592 290499

Características paquete 10 uds

Cantidad: 10 uds(bolsas individuales)/caja
SKU: MASK-ST-00031.0010
Dimensión: 151,5 x 195 x 131,2 mm
Peso: 130 g

8 436592 290505

Características caja maestra

Cantidad: 60 paquetes/caja
Total cantidad: 600 unidades
Dimensión: 620 x 545 x 234 mm
Peso: 8,5 Kg

CE 2163

EN 149:2001 + A1:2009

Star Care

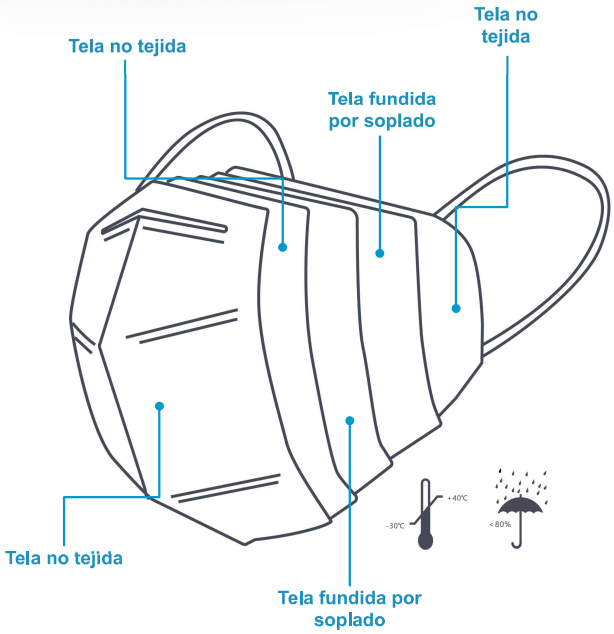
FFP3

Mascarilla filtrante

Mascarilla de protección 99%
filtración para aerosoles

Información técnica

Nombre de producto: Mascarilla de filtración
Clasificación: FFP3 - NR (No reutilizable)
Modelo: MSH
Tamaño: 15,6 x 11,8 cm
Estándar: EN 149:2001 + A1:2009
Composición: 66,7% Tela no tejida, 33,3% tela fundida por soplado
Aviso de alergia: Textil no tejido
Caducidad: Dos años bajo las condiciones de almacenamiento especificadas
Accesorios: Salvaorejas, reguladores de tamaño



Instrucciones para ponerse la mascarilla

1. Sujétela con una mano, con el clip nasal orientado hacia los dedos y las cintas de sujeción colgando.
2. Coloque la mascarilla sobre la cara cubriendo totalmente la nariz y la boca. El clip nasal debe quedar sobre la nariz.
3. Sujete la mascarilla con una mano sobre la barbilla. Tire de la cinta y colóquela detrás de la oreja.
4. Ajuste el clip nasal a la nariz con ambas manos y asegúrese de que los bordes de la mascarilla están en contacto directo con la cara.
5. Haga una prueba de ajuste-fuga para comprobar que se ha puesto la mascarilla de forma correcta. Cubra la mascarilla con las dos manos y exhale con fuerza. Si detecta fugas a través de los bordes, modifique la posición de la mascarilla sobre la cara, reajuste el clip nasal o ajuste la tensión de las cintas de sujeción. Repita este proceso hasta que no detecte ninguna fuga.

CE 0370

EN 149:2001 + A1:2009

Star Care

FFP3

Mascarilla filtrante

Mascarilla de protección 99% filtración
para la contaminación de partículas

Información importante

- Los equipos NR no deben usarse en más de un turno de trabajo.
- Usar bajo las recomendaciones del fabricante, siguiendo las instrucciones del etiquetado.
- Estas mascarillas no aportan oxígeno.
- No usar en atmósferas con baja concentración de oxígeno o zonas poco ventiladas.
- La presencia de características faciales especiales, vello abundante o gafas puede impedir un correcto ajuste de la mascarilla.
- Mantener alejadas de fuentes de calor.
- Guardar en un espacio interior bien ventilado, con humedad inferior al 80% y sin gases corrosivos.

Características de la bolsa individual

Cantidad: 1 ud/bolsa
SKU: MASK-ST-00024.0001
Dimensión: 205 x 130 mm
Peso: 12 g

8 436592 290369

Características del paquete 10 uds

Cantidad: 10 uds(bolsas individuales)/paquete
SKU: MASK-ST-00024.0010
Dimensión: 210 x 195 x 131,2 mm
Peso: 135 g

8 436592 290352

Características de la caja

Cantidad: 60 paquetes/caja
Total cantidad: 600 unidades
Dimensión: 620*545*234 mm

CE 0370

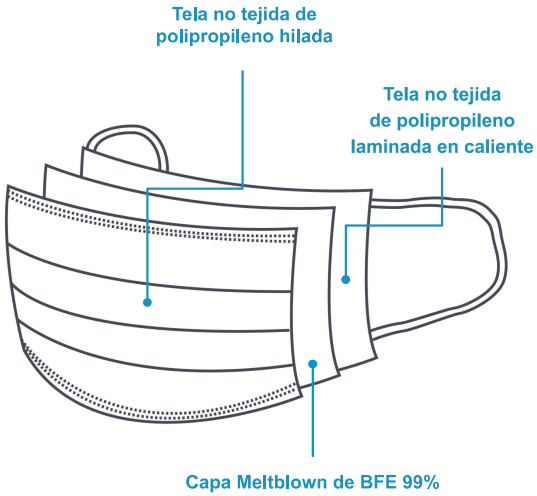
EN 149:2001 + A1:2009

Star Care

Mascarilla quirúrgica (BFE ≥ 98%) Tipo IIR

Información técnica

Tipología: Mascarilla quirúrgica desechable
Tamaño: 17,5 x 9,4 cm
Modelo: BHKZ-001
Estándar: CE: EN 14683-2019 + AC:2019
Eficacia de filtración bacteriana: ≥ 98%
Prestaciones:
Tipo IIR: calidad máxima para quirúrgicas
Resistente a salpicaduras
Estructura: cuerpo de la máscara, pinza nasal y agarre de la máscara
Caducidad: 24 meses
Aviso de alergia: Textil no tejido



Instrucciones para ponerse la mascarilla

1. Con el lado azul hacia fuera, colóquela sobre la nariz y la boca. A continuación, pase las cintas por detrás de las orejas.
2. Presione suavemente el clip nasal para adaptarlo a la nariz.
3. Tire de la parte inferior de la mascarilla para que quede por debajo de la barbilla y compruebe el ajuste.

Información importante

- Material hipoalergénico, polipropileno y resistente al agua incluyendo la pinza nasal flexible.
- Informe de Ensayos CE emitido por TÜV SÜD.
- Condiciones de conservación: Almacenar en lugar con relativa baja humedad, libre de gases corrosivos, bien ventilado y evitando altas temperaturas (>40ºC).

CE

Star Care

Mascarilla quirúrgica (BFE ≥ 98%) Tipo IIR

CARACTERÍSTICAS	ESTÁNDAR	RESULTADOS
Bacterial Filtration Efficiency (BFE)	EN 14683:2019+AC:2019 (E) Anexo B	BFE ≥ 99%
Presión diferencial (ΔP)	EN 14683:2019+AC:2019 (E) Anexo C	ΔP < 38 Pa/cm2
Limpieza Microbiana	EN 14683:2019+AC:2019 (E) Anexo D	CFU/g < 20
Penetración de sangre sintética	ISO 22609:2004	No detectada

Fuente: Test Report No.: 200193327 (TÜV SÜD)

Características bolsa 10 uds

Cantidad: 10 uds/bolsa
SKU: MASK-ST-00032.0010
Dimensión: 210 x 120 x 23 mm
Peso: 25 g

8 436592 290529

Características de la caja

Cantidad: 100 bolsas/caja
Total cantidad: 1000 unidades
Dimensión: 525 x 435 x 270 mm

CE

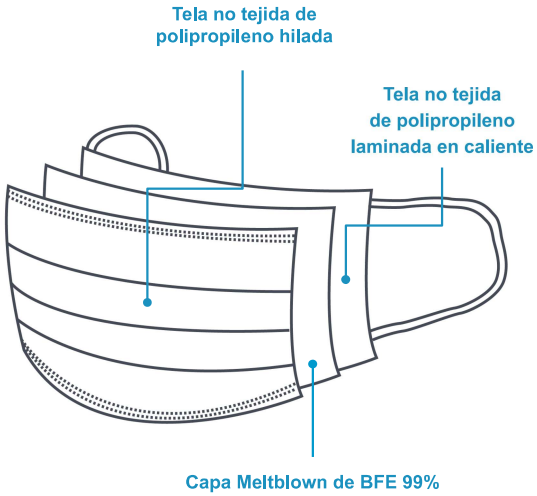
Star Care

Mascarilla Quirúrgica Infantil. Tipo IIR (BFE ≥ 98%)

De 6 a 9 años y de 10 a 12 años

Información técnica

Tipología: Mascarilla quirúrgica infantil. Tipo IIR. Desechable
Estándar: CE: EN 14683-2019 + AC:2019
Tamaño:
150 x 65 mm (6-9 años)
170 x 70 mm (10-12 años)
Eficacia de filtración bacteriana: ≥ 98%
Prestaciones: resistente a salpicaduras
Estructura: cuerpo de la máscara, pinza nasal y agarre de la máscara
Caducidad: 24 meses
Aviso de alergia: Textil no tejido
Unidades / paquete: 10 unidades
Accesorios: Reguladores de tamaño incluidos



Instrucciones para ponerse la mascarilla

1. Con el lado azul hacia fuera, colóquela sobre la nariz y la boca. A continuación, pase las cintas por detrás de las orejas.
2. Presione suavemente el clip nasal para adaptarlo a la nariz.
3. Tire de la parte inferior de la mascarilla para que quede por debajo de la barbilla y compruebe el ajuste.

Información importante

- Material hipoalergénico, polipropileno y resistente al agua incluyendo la pinza nasal flexible.
- Informe de Ensayos CE emitido por TÜV SÜD.
- Condiciones de conservación: Almacenar en lugar con relativa baja humedad, libre de gases corrosivos, bien ventilado y evitando altas temperaturas (>40ºC).

CE

Star Care

Mascarilla Quirúrgica Infantil. Tipo IIR (BFE ≥ 98%)

De 6 a 9 años y de 10 a 12 años

CARACTERÍSTICAS	ESTÁNDAR	RESULTADOS
Bacterial Filtration Efficiency (BFE)	EN 14683:2019+AC:2019	BFE ≥ 99%
Presión diferencial (ΔP)	EN 14683:2019+AC:2019	ΔP < 38 Pa/cm2
Limpieza Microbiana	EN 14683:2019+AC:2019	CFU/g < 20
Penetración de sangre sintética	ISO 22609:2004	No detectada

Fuente: Test Report No.: 200193327 (TÜV SÜD)

Características del paquete

Cantidad: 10 uds/paquete
SKU: MASK-ST-00025.0010
Dimensión: 215 x 115
Peso: 21 g

Tamaño: 6 a 9 años

8 436592 290376

Tamaño: 10 a 12 años

8 436592 290390

Características de la caja

Cantidad: 100 paquetes/caja
Total cantidad: 1.000 unidades
Dimensión: 500 x 370 x 230 mm

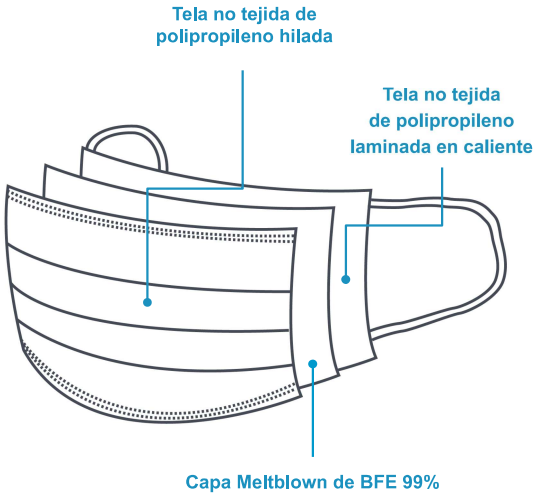
CE

Star Care

Mascarilla higiénica (BFE ≥ 98%)

Información técnica

Tipología: Mascarilla higiénica desechable
Estándar: EN 14683-2019 + AC:2019, YY/T0969-2013
Tamaño: 17,5 x 9,5 cm
Eficacia de filtración bacteriana: ≥ 95%
Prestaciones: resistente a salpicaduras
Estructura: cuerpo de la máscara, pinza nasal y agarre de la máscara
Caducidad: 12 meses
Aviso de alergia: Textil no tejido



Instrucciones para ponerse la mascarilla

1. Con el lado azul hacia fuera, colóquela sobre la nariz y la boca. A continuación, pase las cintas por detrás de las orejas.
2. Presione suavemente el clip nasal para adaptarlo a la nariz.
3. Tire de la parte inferior de la mascarilla para que quede por debajo de la barbilla y compruebe el ajuste.

Información importante

- Material hipoalergénico, polipropileno y resistente al agua incluyendo la pinza nasal flexible.
- Informe de Ensayos CE emitido por TÜV SÜD.
- Condiciones de conservación: Almacenar en lugar con relativa baja humedad, libre de gases corrosivos, bien ventilado y evitando altas temperaturas (>40ºC).

Star Care

Mascarilla higiénica (BFE ≥ 98%)

CARACTERÍSTICAS	ESTÁNDAR	RESULTADOS
Bacterial Filtration Efficiency (BFE)	EN 14683:2019+AC:2019 (E) Anexo B	BFE ≥ 99%
Presión diferencial (ΔP)	EN 14683:2019+AC:2019 (E) Anexo C	ΔP = 54 Pa/cm2

Fuente: Test Report No.: 60379483 001 (TÜV SÜD)

Características bolsa 10 uds

Cantidad: 10 uds/bolsa
SKU: MASK-ST-00027.0010
Dimensión: 210 x 120 x 23 mm
Peso: 25 g

8 436592 290413

Características de la caja

Cantidad: 100 bolsas/caja
Total cantidad: 1000 unidades
Dimensión: 590 x 435 x 280 mm

cantabria labs
SPAIN

Star Care

Gel Hidroalcohólico higienizante de manos 100 ml

- Fabricante: Cantabria Labs, especialista en productos de cuidado de la piel a través de las prestigiosas marcas Heliocare, Endocare, Neostrata, Dermacare, Neoretin o Radiocare.
- Gel hidroalcohólico destinado a la limpieza en profundidad de las manos y las superficies de contacto de uso cotidiano.
- Proporciona una limpieza eficiente gracias a su fórmula optimizada con grado alcohólico del 70% v/v .
- Su contenido en glicerina mantiene el equilibrio hídrico en la piel, minimiza los daños derivados del uso continuado de alcohol y aporta confort y humectación sin dejar residuos.

SKU: GEL-ST-00001.0100

EAN: 8436574361278

Composición:

1. Alcohol Denat (70% v/v)
2. Phenoxyetanol (0,9% p/p)
3. Excipientes c.s.p 100%

Información técnica:

1. 100 ml: botella PET con tapón flip-top de fácil dosificación.
2. Registro CPNP 3297893
3. PAO / Caducidad: No aplica acorde al reglamento (CE) Nº 1223/2009

Aplicación y modo de empleo:

- USO EXTERNO. No ingerir. Evitar contacto directo con ojos y mucosas. Tratamiento higiénico de manos, utensilios y superficies por fricción.
- Para su correcto uso se recomienda su aplicación sobre la piel sana, limpia y seca. Masajear por todas las manos incluidas las zonas interdigitales y dejar secar al aire sin aclarado.

CARACTERÍSTICAS DEL PAQUETE / PALET

- **Cantidad:** 34 piezas/paquete
- **Dimensión:** 275 x 200 x 125 mm
- **Peso:** 3,62 kg

- **Cantidad:** 112 paquetes/palet
- **Total cantidad:** 3.808 piezas
- **Dimensión:** 1200 x 800 x 1270 mm
- **Peso pallet:** 431 kg

Star Care

Certificados

Star Care

Mascarilla FFP2

Certificado

Mascarilla FFP2

Star Care

Declaración de Conformidad

DECLARACIÓN UE DE CONFORMIDAD

La presente Declaración de Conformidad, expedida bajo la exclusiva responsabilidad del fabricante, **Huizhou Hengda Innovation Communication Equipment Co., Ltd.**, ubicado en Building A, Wanli Industrial Co., Ltd., Dalongkeng, Ganpo, Zhenlong Town, Huiyang District, Huizhou City, Guandgdong Province, China,

CERTIFICA

Que el siguiente equipo de protección individual (EPI)

Modelo: MSH

Descripción del producto: Mascarilla de filtración FFP2

Cumple con las exigencias del Reglamento (UE) 2016/425, de 9 de marzo de 2016 relativo a los equipos de protección individual, incluidos los requisitos esenciales de salud y seguridad especificados en el anexo II, y de las normas nacionales que transpongan las siguientes normas armonizadas europeas:

EN 149:2001+A1:2009

Asimismo, el modelo es idéntico al EPI que está sujeto al Examen UE de Tipo (módulo B del Reglamento (UE) 2016/425) al que se hace referencia en el certificado nº:

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

Expedido por:

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

El modelo indicado está sujeto al procedimiento de evaluación de la conformidad con el tipo basada en el control interno de la producción más control supervisado de los productos a intervalos aleatorios (Módulo C2), según Reglamento (UE) 2016/425, bajo la supervisión del Organismo Notificado Universal Certification and Surveillance Services Trade Co. (NB 2163)

Firmado por y en nombre de:

Fdo.: Jacky Wang

Nombre: Jacky Wang

Cargo: CEO

Lugar y fecha: HUIZHOU,CHINA 12,06, 2020

Mascarilla FFP2

Star Care

Certificado CE

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
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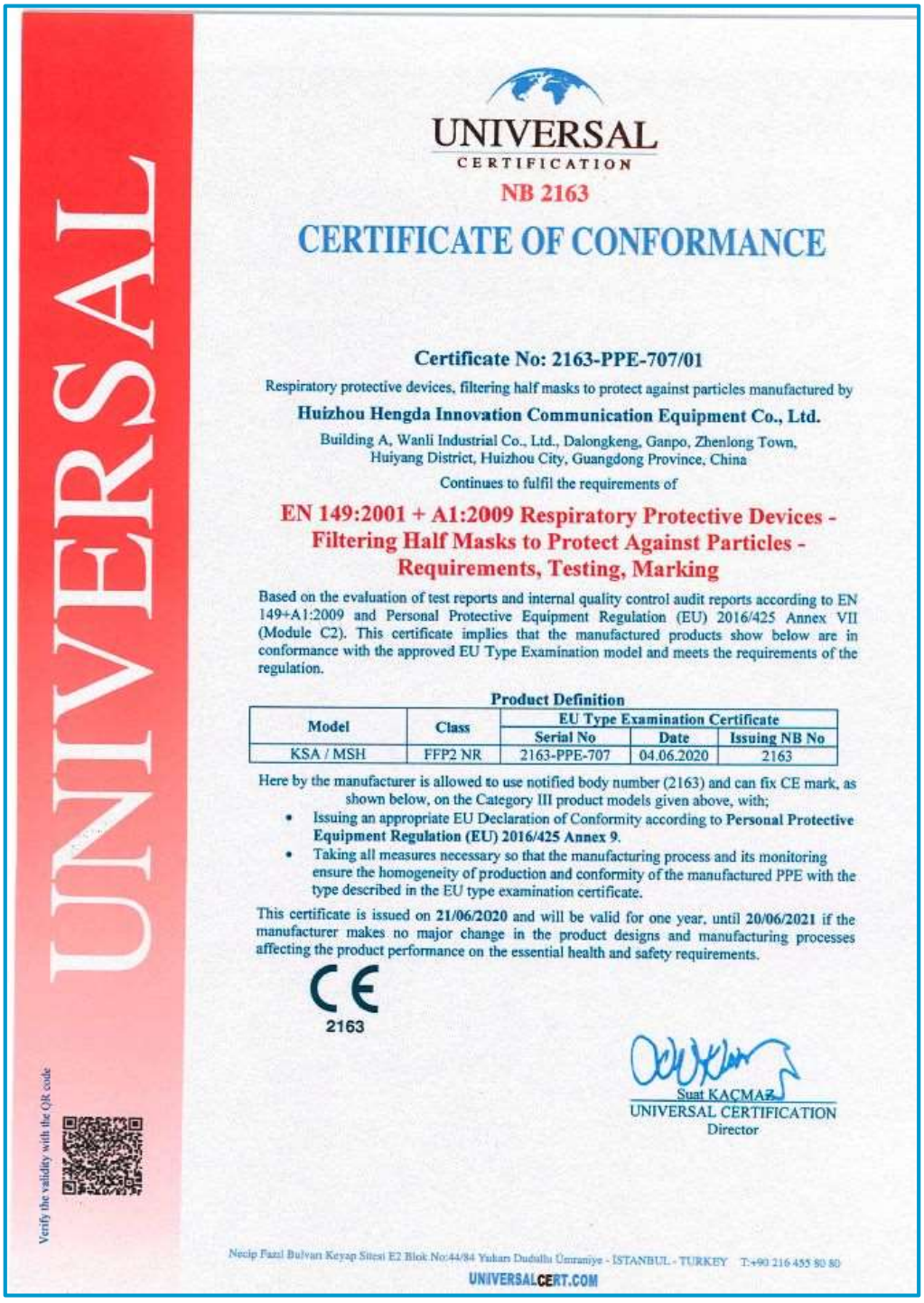
Mascarilla FFP2

Star Care

Certificado CE



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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

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Certificado CE

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TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 04.06.2020 / 2163-KKD-708

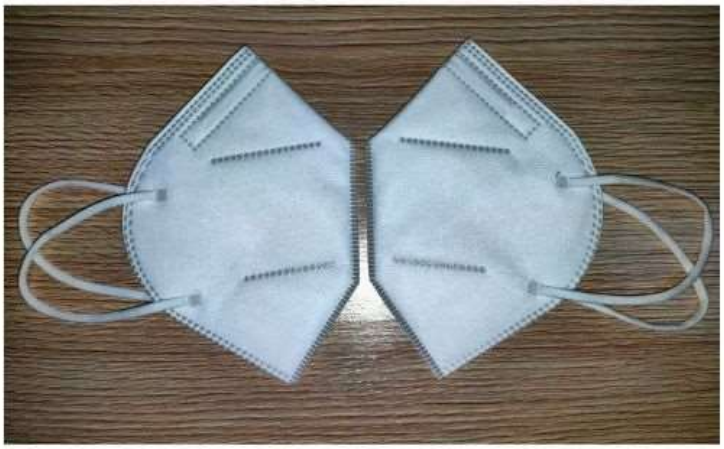
Manufacturer: Huizhou Hengda Innovation Communication Equipment Co., Ltd.
Address: Building A, Wanli Industrial Co., Ltd., Dalongkeng, Ganpo, Zhenlong Town, Huiyang District, Huizhou City, Guangdong Province, China

This report is for the, given above, manufacturer prepared according to the test results obtained from BEFITLAB Test Technology Shanghai Co., Ltd. accredited by IAS (International Accreditation Service), signatory to ILAC MRA, with number TL-787 for the product identified below, dated 21.05.2020 with Serial Id BT20051301624-1 based on EN 149: 2001 + A1: 2009 standard. The sampling of the product is conducted under our supervision for testing from the manufacturing site of the cient.

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

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

Product Description: Particle Filtering Half Mask
Classification: FFP2 NR
Brand Name: KSA **Model:** MSH



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Mascarilla FFP2

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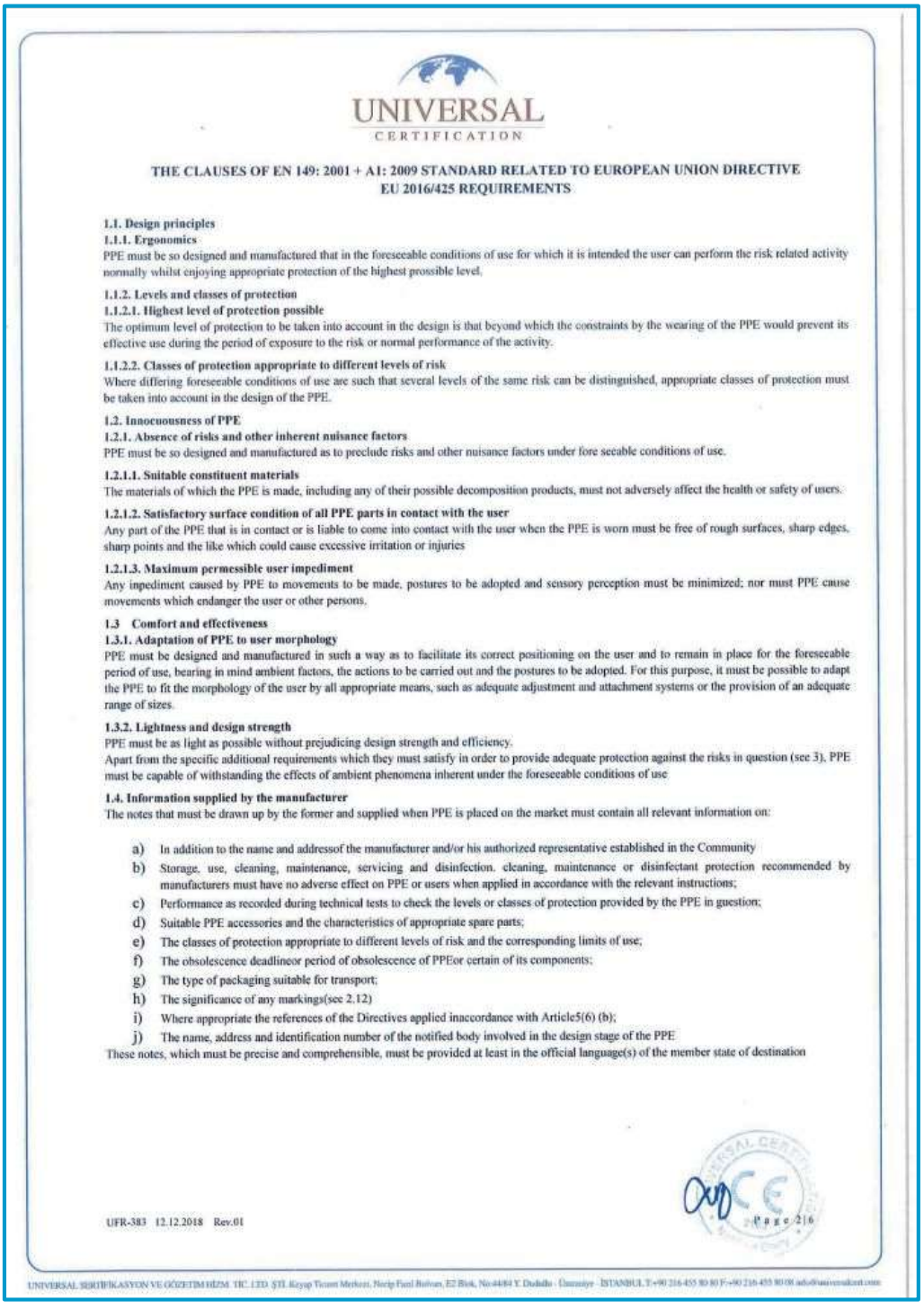
Certificado CE



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THE CLAUSES OF EN 149: 2001 + A1: 2009 STANDARD RELATED TO EUROPEAN UNION DIRECTIVE EU 2016/425 REQUIREMENTS

1.1. Design principles

1.1.1. Ergonomics

PPE must be so designed and manufactured that in the foreseeable conditions of use for which it is intended the user can perform the risk related activity normally whilst enjoying appropriate protection of the highest prossible level.

1.1.2. Levels and classes of protection

1.1.2.1. Highest level of protection possible

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

1.1.2.2. Classes of protection appropriate to different levels of risk

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

1.2. Innocuousness of PPE

1.2.1. Absence of risks and other inherent nuisance factors

PPE must be so designed and manufactured as to preclude risks and other nuisance factors under fore seeable conditions of use.

1.2.1.1. Suitable constituent materials

The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.

1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user

Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries

1.2.1.3. Maximum permessible user impediment

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

1.3 Comfort and effectiveness

1.3.1. Adaptation of PPE to user morphology

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

1.3.2. Lightness and design strength

PPE must be as light as possible without prejudicing design strength and efficiency.

Apart from the specific additional requirements which they must satisfy in order to provide adequate protection against the risks in question (see 3), PPE must be capable of withstanding the effects of ambient phenomena inherent under the foreseeable conditions of use

1.4. Information supplied by the manufacturer

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

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

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

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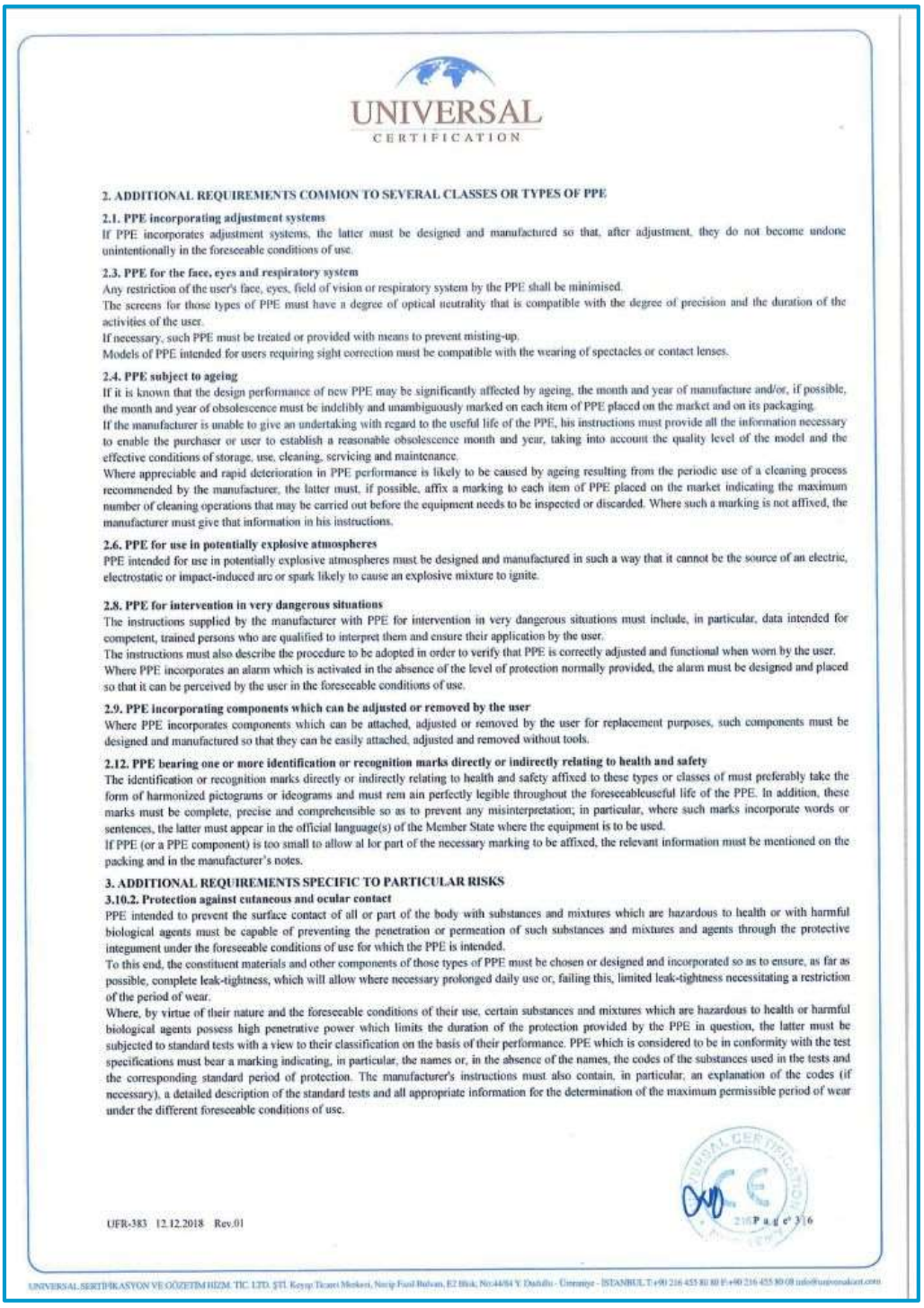
Mascarilla FFP2

Star Care

Certificado CE



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

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

2.3. PPE for the face, eyes and respiratory system
Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised.
The screens for those types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user.
If necessary, such PPE must be treated or provided with means to prevent misting-up.
Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.

2.4. PPE subject to ageing
If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging.
If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, his instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.
Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions.

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

2.8. PPE for intervention in very dangerous situations
The instructions supplied by the manufacturer with PPE for intervention in very dangerous situations must include, in particular, data intended for competent, trained persons who are qualified to interpret them and ensure their application by the user.
The instructions must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.
Where PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, the alarm must be designed and placed so that it can be perceived by the user in the foreseeable conditions of use.

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

2.12. PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety
The identification or recognition marks directly or indirectly relating to health and safety affixed to these types or classes of must preferably take the form of harmonized pictograms or ideograms and must rem ain perfectly legible throughout the foreseeableuseful life of the PPE. In addition, these marks must be complete, precise and comprehensible so as to prevent any misinterpretation; in particular, where such marks incorporate words or sentences, the latter must appear in the official language(s) of the Member State where the equipment is to be used.
If PPE (or a PPE component) is too small to allow al lor part of the necessary marking to be affixed, the relevant information must be mentioned on the packing and in the manufacturer's notes.

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS
3.10.2. Protection against cutaneous and ocular contact
PPE intended to prevent the surface contact of all or part of the body with substances and mixtures which are hazardous to health or with harmful biological agents must be capable of preventing the penetration or permeation of such substances and mixtures and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.
To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear.
Where, by virtue of their nature and the foreseeable conditions of their use, certain substances and mixtures which are hazardous to health or harmful biological agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, in the absence of the names, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.

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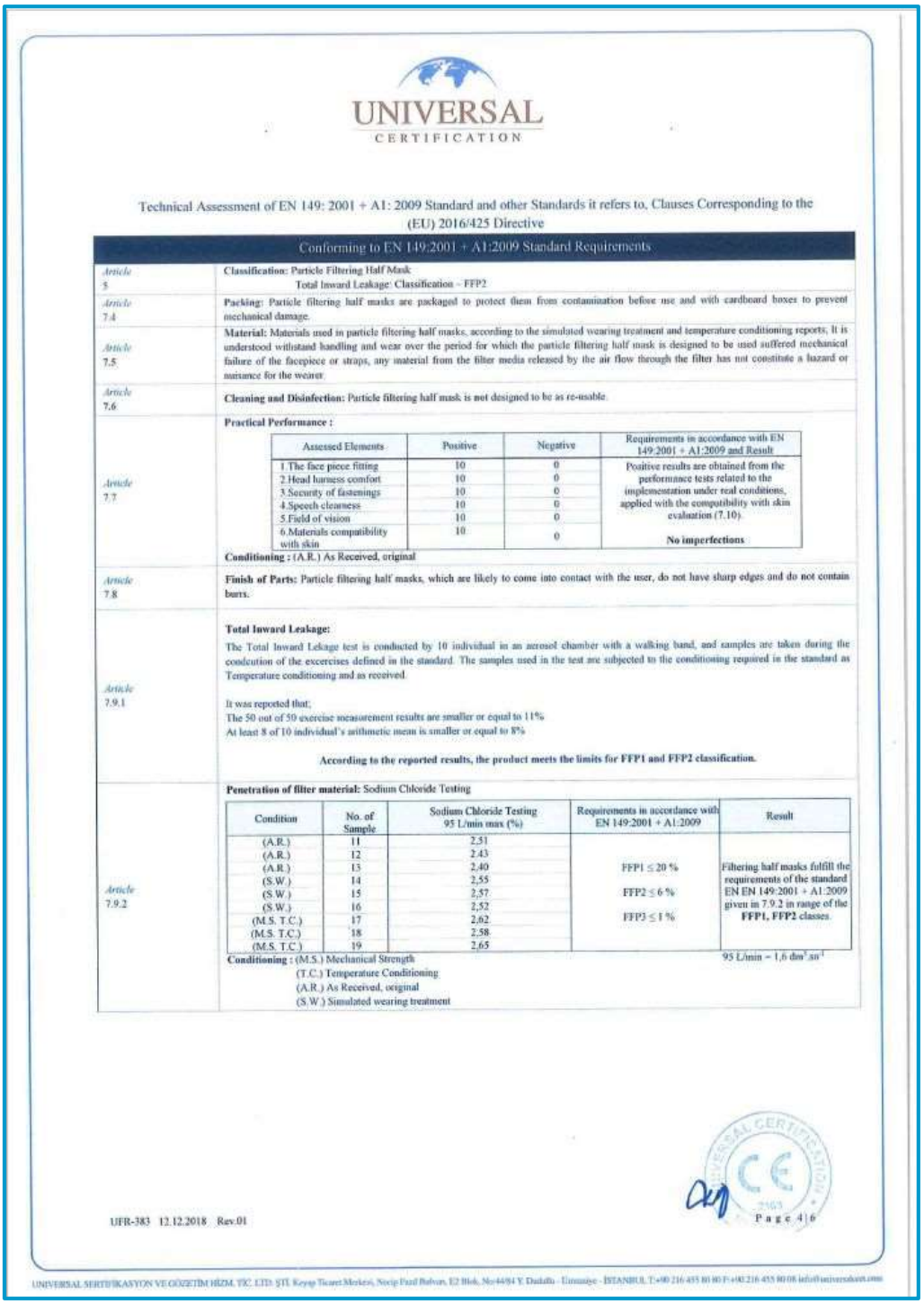
Mascarilla FFP2

Star Care

Certificado CE



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CERTIFICATION

Technical Assessment of EN 149: 2001 + A1: 2009 Standard and other Standards it refers to, Clauses Corresponding to the (EU) 2016/425 Directive

Conforming to EN 149:2001 + A1:2009 Standard Requirements	
Article 5	**Classification:** Particle Filtering Half Mask Total Inward Leakage: Classification – FFP2
Article 7.4	**Packing:** Particle filtering half masks are packaged to protect them from contamination before use and with cardboard boxes to prevent mechanical damage.
Article 7.5	**Material:** Materials used in particle filtering half masks, according to the simulated wearing treatment and temperature conditioning reports, It is understood withstand handling and wear over the period for which the particle filtering half mask is designed to be used suffered mechanical failure of the facepiece or straps, any material from the filter media released by the air flow through the filter has not constitute a hazard or nuisance for the wearer.
Article 7.6	**Cleaning and Disinfection:** Particle filtering half mask is not designed to be as re-usable.
Article 7.7	**Practical Performance :** Assessed Elements / Positive / Negative / Requirements in accordance with EN 149:2001 + A1:2009 and Result 1.The face piece fitting — 10 — 0 2.Head harness comfort — 10 — 0 3.Security of fastenings — 10 — 0 4.Speech clearness — 10 — 0 5.Field of vision — 10 — 0 6.Materials compatibility with skin — 10 — 0 Positive results are obtained from the performance tests related to the implementation under real conditions, applied with the compatibility with skin evaluation (7.10). **No imperfections** **Conditioning :** (A.R.) As Received, original
Article 7.8	**Finish of Parts:** Particle filtering half masks, which are likely to come into contact with the user, do not have sharp edges and do not contain burrs.
Article 7.9.1	**Total Inward Leakage:** The Total Inward Leakage test is conducted by 10 individual in an aerosol chamber with a walking band, and samples are taken during the conduction of the excercises defined in the standard. The samples used in the test are subjected to the conditioning required in the standard as Temperature conditioning and as received. It was reported that; The 50 out of 50 exercise measurement results are smaller or equal to 11% At least 8 of 10 individual's arithmetic mean is smaller or equal to 8% **According to the reported results, the product meets the limits for FFP1 and FFP2 classification.**
Article 7.9.2	**Penetration of filter material:** Sodium Chloride Testing Condition / No. of Sample / Sodium Chloride Testing 95 L/min max (%) / Requirements in accordance with EN 149:2001 + A1:2009 / Result (A.R.) 11 2,51 (A.R.) 12 2,43 (A.R.) 13 2,40 (S.W.) 14 2,55 (S.W.) 15 2,57 (S.W.) 16 2,52 (M.S. T.C.) 17 2,62 (M.S. T.C.) 18 2,58 (M.S. T.C.) 19 2,65 FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 % Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the **FFP1, FFP2** classes. **Conditioning :** (M.S.) Mechanical Strength (T.C.) Temperature Conditioning (A.R.) As Received, original (S.W.) Simulated wearing treatment 95 L/min = 1,6 $dm^3.s^{-1}$

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

Mascarilla FFP2

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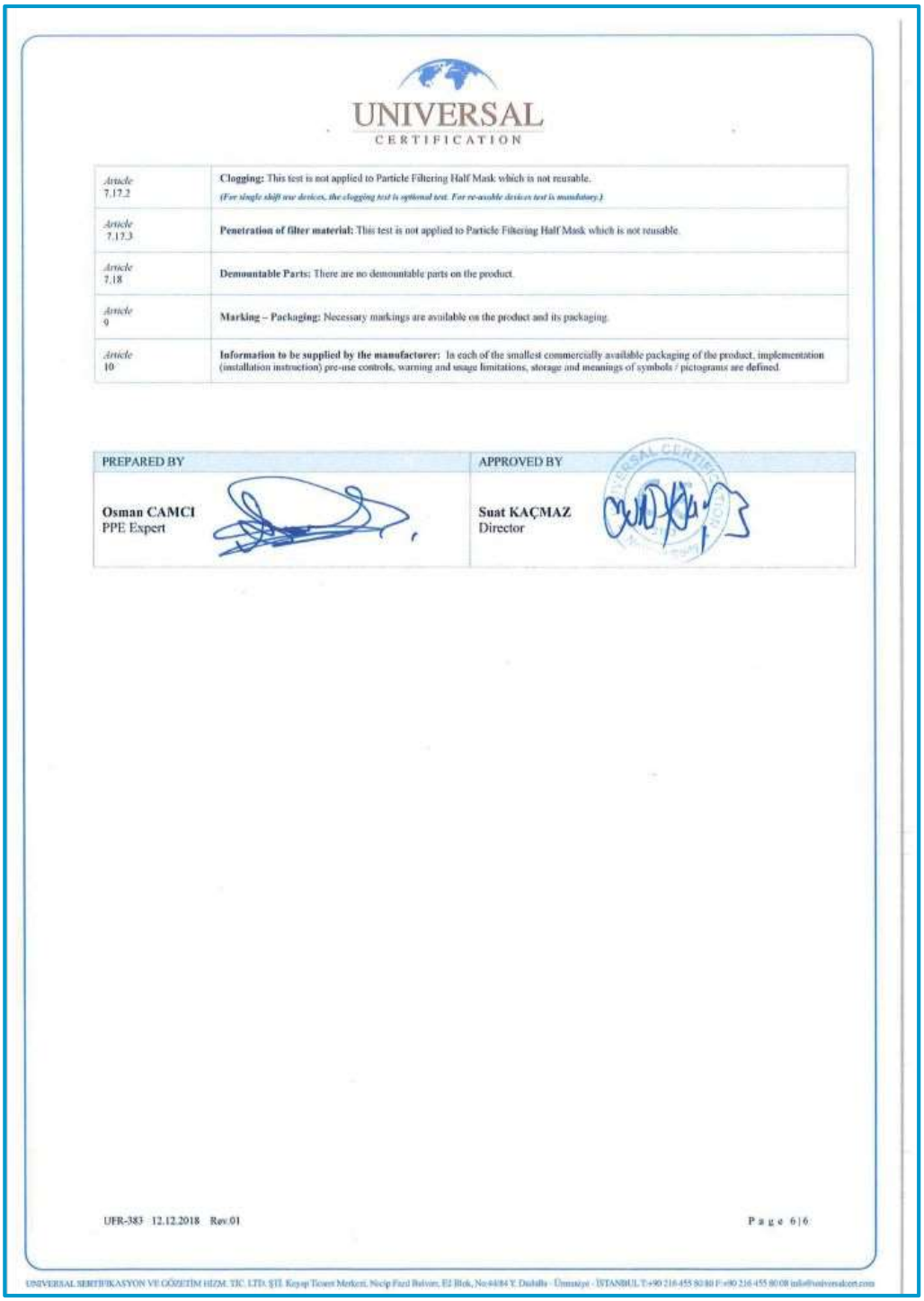

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Article 7.17.2	**Clogging:** This test is not applied to Particle Filtering Half Mask which is not reusable. *(For single shift use devices, the clogging test is optional test. For re-usable devices test is mandatory.)*
Article 7.17.3	**Penetration of filter material:** This test is not applied to Particle Filtering Half Mask which is not reusable.
Article 7.18	**Demountable Parts:** There are no demountable parts on the product.
Article 9	**Marking – Packaging:** Necessary markings are available on the product and its packaging.
Article 10	**Information to be supplied by the manufacturer:** In each of the smallest commercially available packaging of the product, implementation (installation instruction) pre-use controls, warning and usage limitations, storage and meanings of symbols / pictograms are defined.

PREPARED BY	APPROVED BY
Osman CAMCI PPE Expert	**Suat KAÇMAZ** Director

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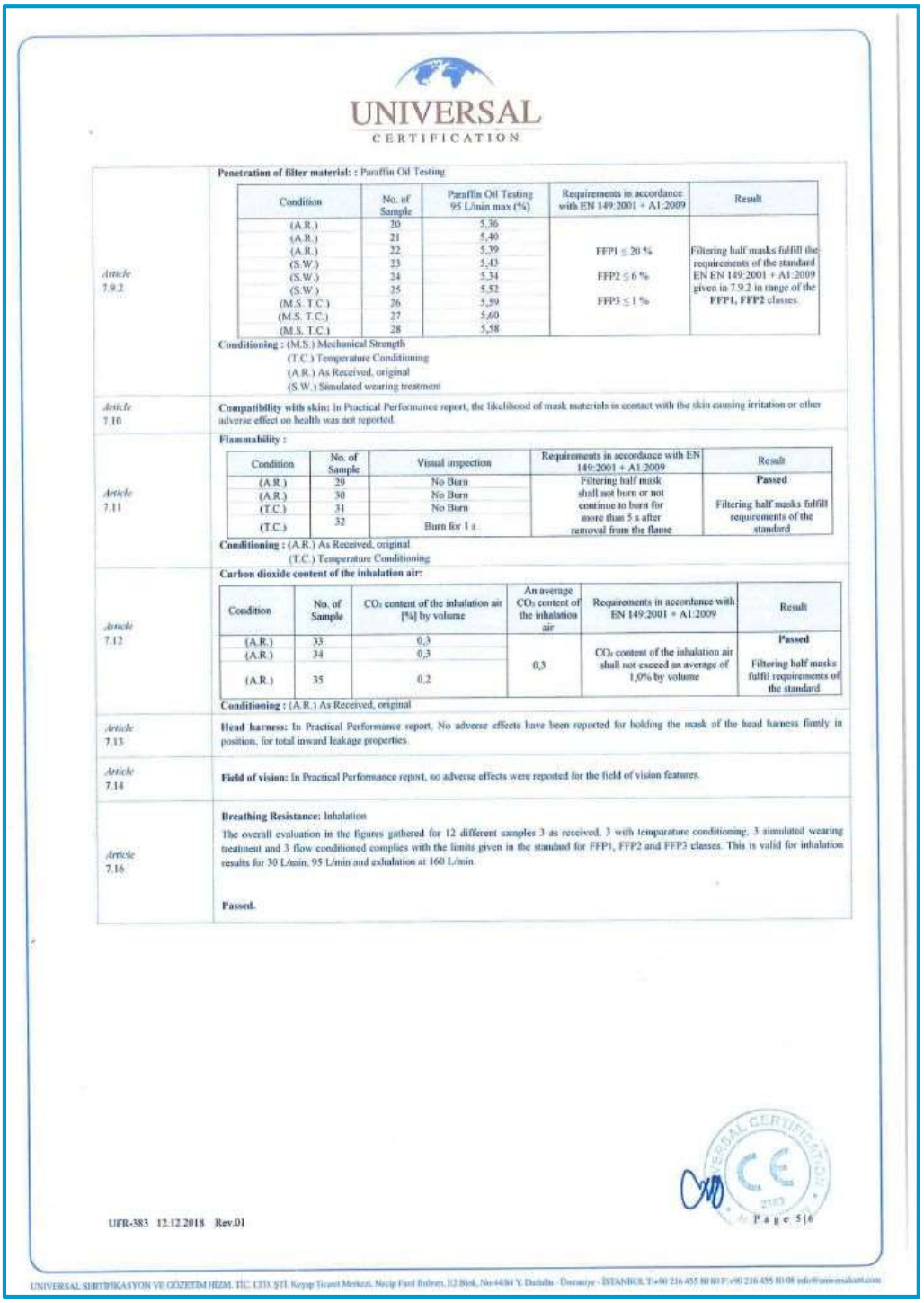

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Article 7.9.2

Penetration of filter material: : Paraffin Oil Testing

Condition	No. of Sample	Paraffin Oil Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	20	5,36		
(A.R.)	21	5,40		
(A.R.)	22	5,39	FFP1 ≤ 20 %	Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the **FFP1, FFP2** classes.
(S.W.)	23	5,43		
(S.W.)	24	5,34	FFP2 ≤ 6 %	
(S.W.)	25	5,52		
(M.S. T.C.)	26	5,59	FFP3 ≤ 1 %	
(M.S. T.C.)	27	5,60		
(M.S. T.C.)	28	5,58		

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

Article 7.10

Compatibility with skin: In Practical Performance report, the likelihood of mask materials in contact with the skin causing irritation or other adverse effect on health was not reported.

Article 7.11

Flammability :

Condition	No. of Sample	Visual inspection	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	29	No Burn	Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame	**Passed**
(A.R.)	30	No Burn		
(T.C.)	31	No Burn		Filtering half masks fulfill requirements of the standard
(T.C.)	32	Burn for 1 s		

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

Article 7.12

Carbon dioxide content of the inhalation air:

Condition	No. of Sample	CO_2 content of the inhalation air [%] by volume	An average CO_2 content of the inhalation air	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	33	0,3	0,3	CO_2 content of the inhalation air shall not exceed an average of 1,0% by volume	**Passed** Filtering half masks fulfil requirements of the standard
(A.R.)	34	0,3			
(A.R.)	35	0,2			

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

Article 7.13

Head harness: In Practical Performance report, No adverse effects have been reported for holding the mask of the head harness firmly in position, for total inward leakage properties.

Article 7.14

Field of vision: In Practical Performance report, no adverse effects were reported for the field of vision features.

Article 7.16

Breathing Resistance: Inhalation

The overall evaluation in the figures gathered for 12 different samples 3 as received, 3 with temparature conditioning, 3 simulated wearing treatment and 3 flow conditioned complies with the limits given in the standard for FFP1, FFP2 and FFP3 classes. This is valid for inhalation results for 30 L/min, 95 L/min and exhalation at 160 L/min.

Passed.

UFR-383 12.12.2018 Rev.01

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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

ENAC CERTIFICACIÓN

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:*
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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 *BRAND*	MSH
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
INFORME DE ENSAYO *TEST REPORT*	S20080700801E-R1 issued by Shenzhen NTEK Testing Technology Co., Ltd. (NTEK)

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Declaración de conformidad

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.

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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:*			**kontrolliert von** / *reviewed by:*		
Lucy Jiang			Angela Chen		
Jun. 28, 2020 Lucy Jiang / Assistant Project Engineer			Jun. 28, 2020 Angela Chen / Department Manager		
Datum *Date*	**Name / Stellung** *Name / Position*	**Unterschrift** *Signature*	**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*

Dieser Prüfbericht bezieht sich nur auf das o.g. Prüfmuster und darf ohne Genehmigung der Prüfstelle nicht auszugsweise vervielfältigt werden. Dieser Bericht berechtigt nicht zur Verwendung eines Prüfzeichens.
This test report only relates to the a. m. test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any test mark.

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

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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

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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

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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.

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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.

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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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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

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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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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.

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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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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	--

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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

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