Star Care

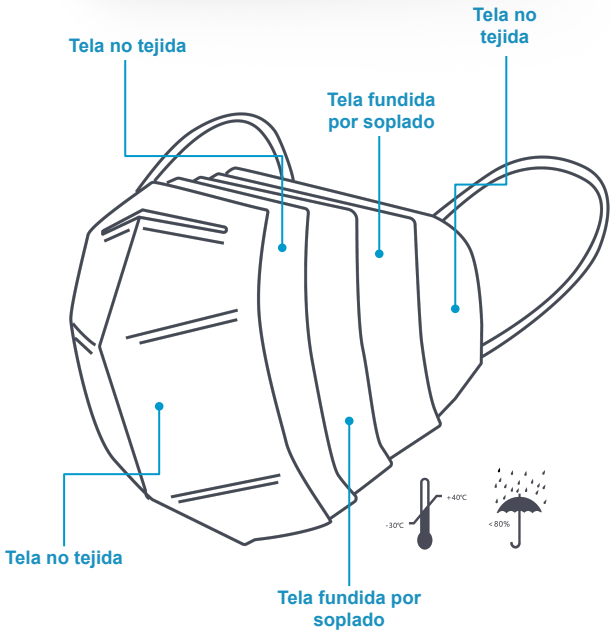
FFP2

Mascarilla filtrante

Mascarilla de protección 94% filtración para la contaminación de partículas

Información técnica

Nombre de producto: Mascarilla de filtración
Clasificación: FFP2 (KN95)
Modelo: MSH
Tamaño: 15,7 x 10,7 cm
Estándar: EN 149:2001 + A1:2009, GB2626:2006
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



SKU: MASK ST-00011.0040

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

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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 del paquete

Cantidad: 40 uds(bolsas individuales)/paquete
SKU: MASK-ST-00011.0040
Dimensión: 141,5 x 225 x 131,2 mm

8 436592 290062

Características de la bolsa individual

Cantidad: 1 ud/bolsa
SKU: MASK-ST-00011.0001
Dimensión: 130 x 130 mm

8 436592 290079

Características de la caja

Cantidad: 12 paquetes/caja
Total cantidad: 480 unidades
Dimensión: 550 x 450 x 250 mm

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EN 149:2001 + A1:2009

Mascarilla FFP2

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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

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

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Mascarilla FFP2

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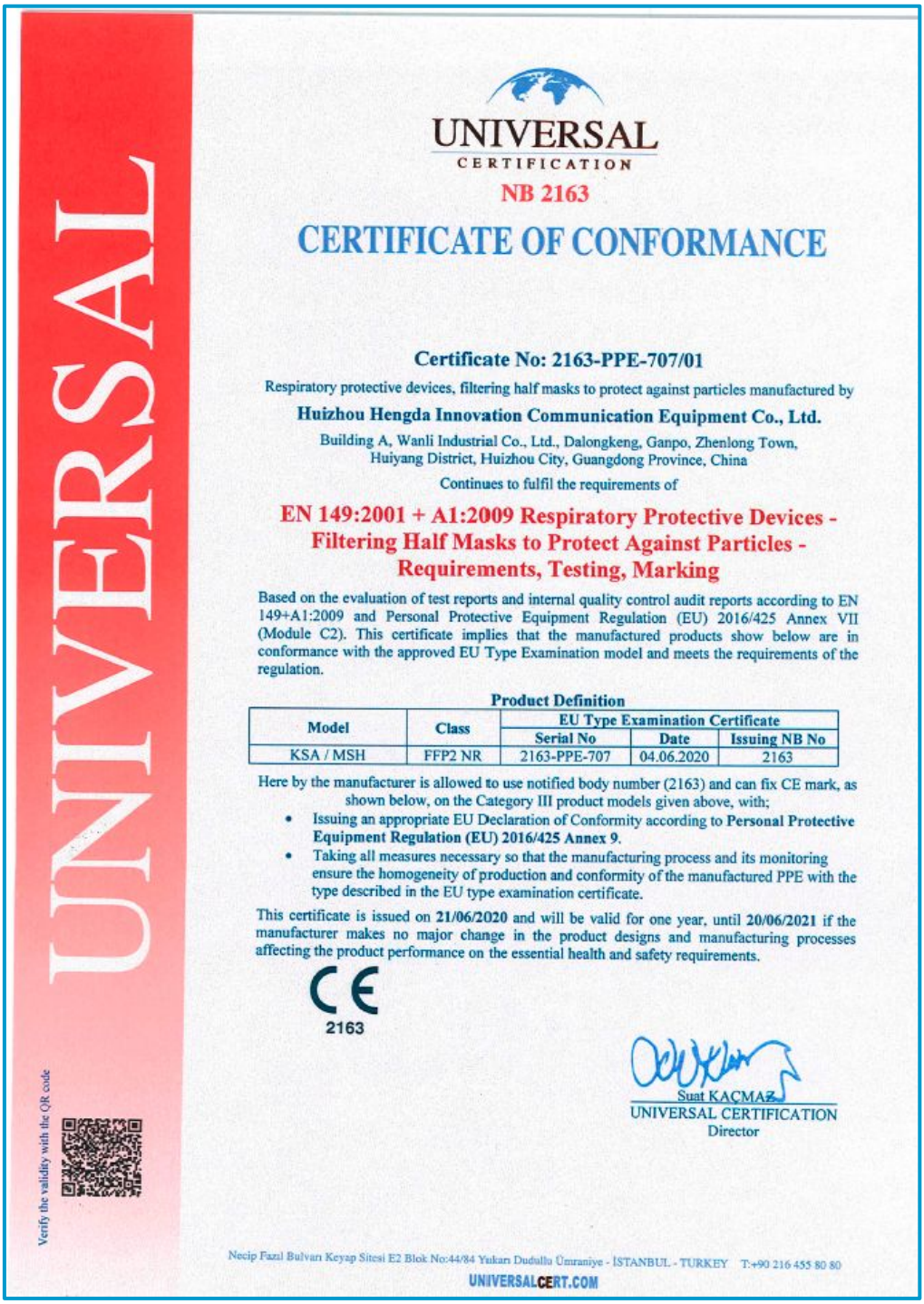
Certificado CE



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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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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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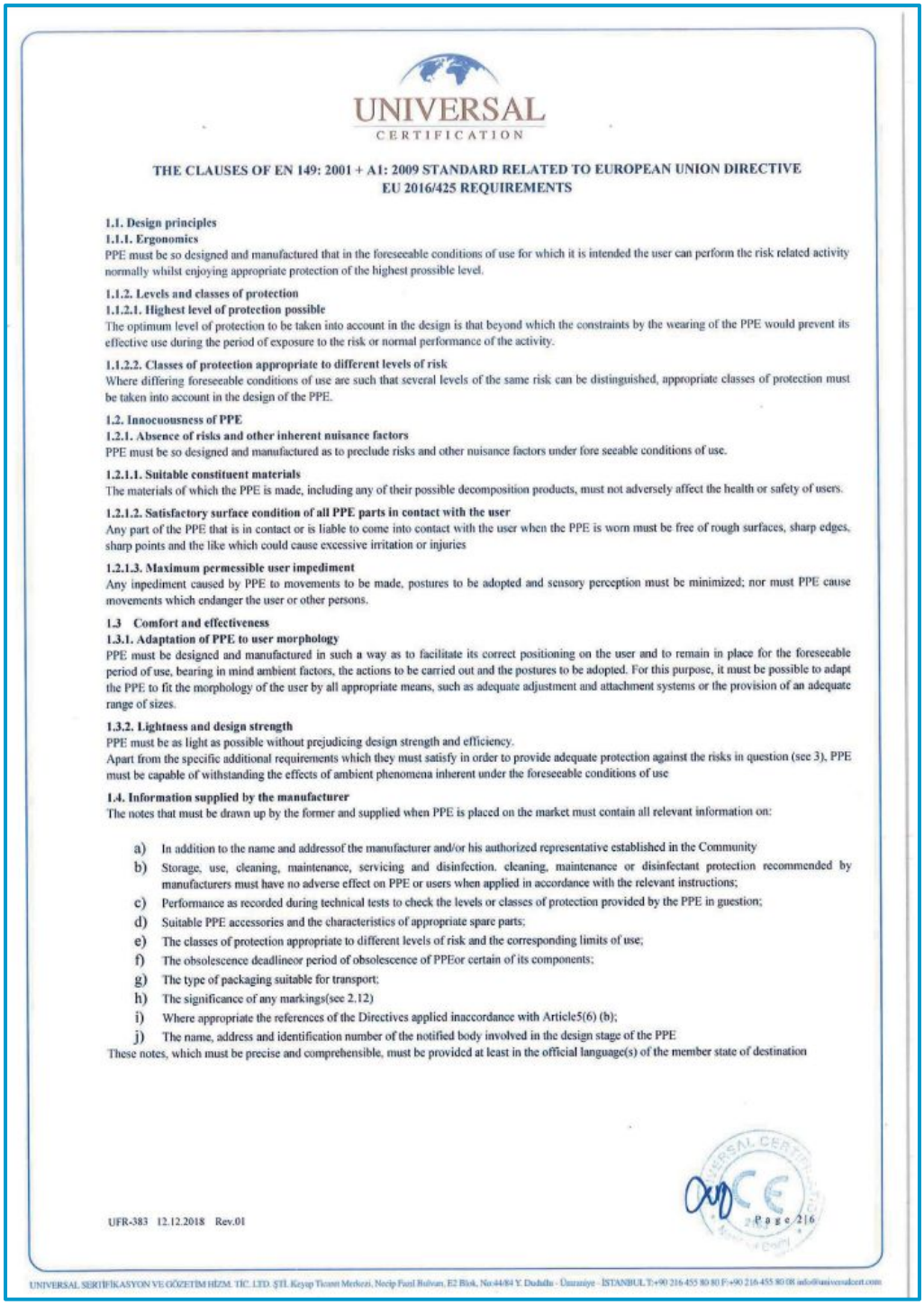

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THE CLAUSES OF EN 149: 2001 + A1: 2009 STANDARD RELATED TO EUROPEAN UNION DIRECTIVE EU 2016/425 REQUIREMENTS

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 possible 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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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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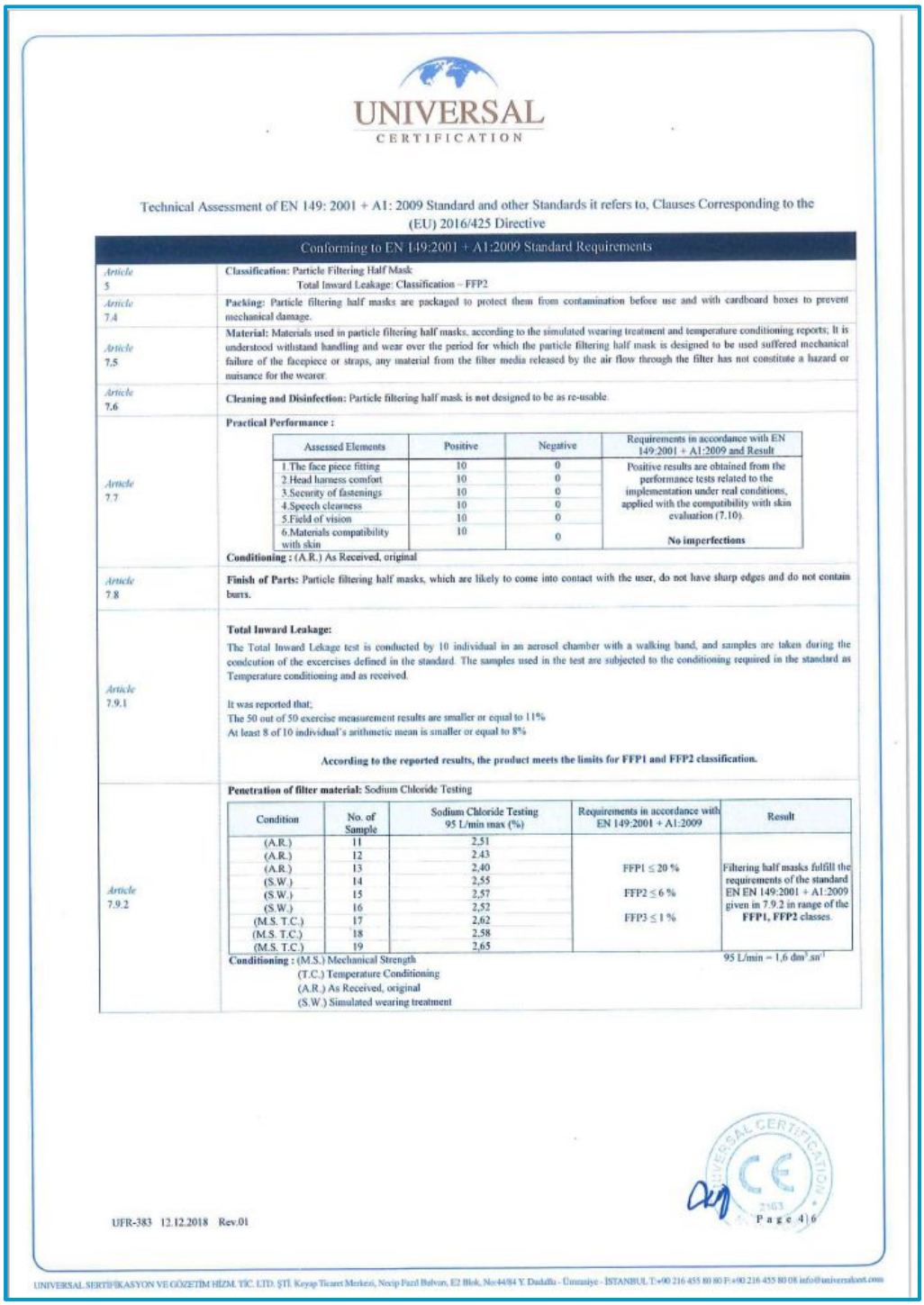
Certificado CE



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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 Lekage test is conducted by 10 individual in an aerosol chamber with a walking band, and samples are taken during the condcution of the excercises defined in the standard. The samples used in the test are subjected to the conditioning required in the standard as Temperature conditioning and as received. 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 $dm^3.sn^{-1}$

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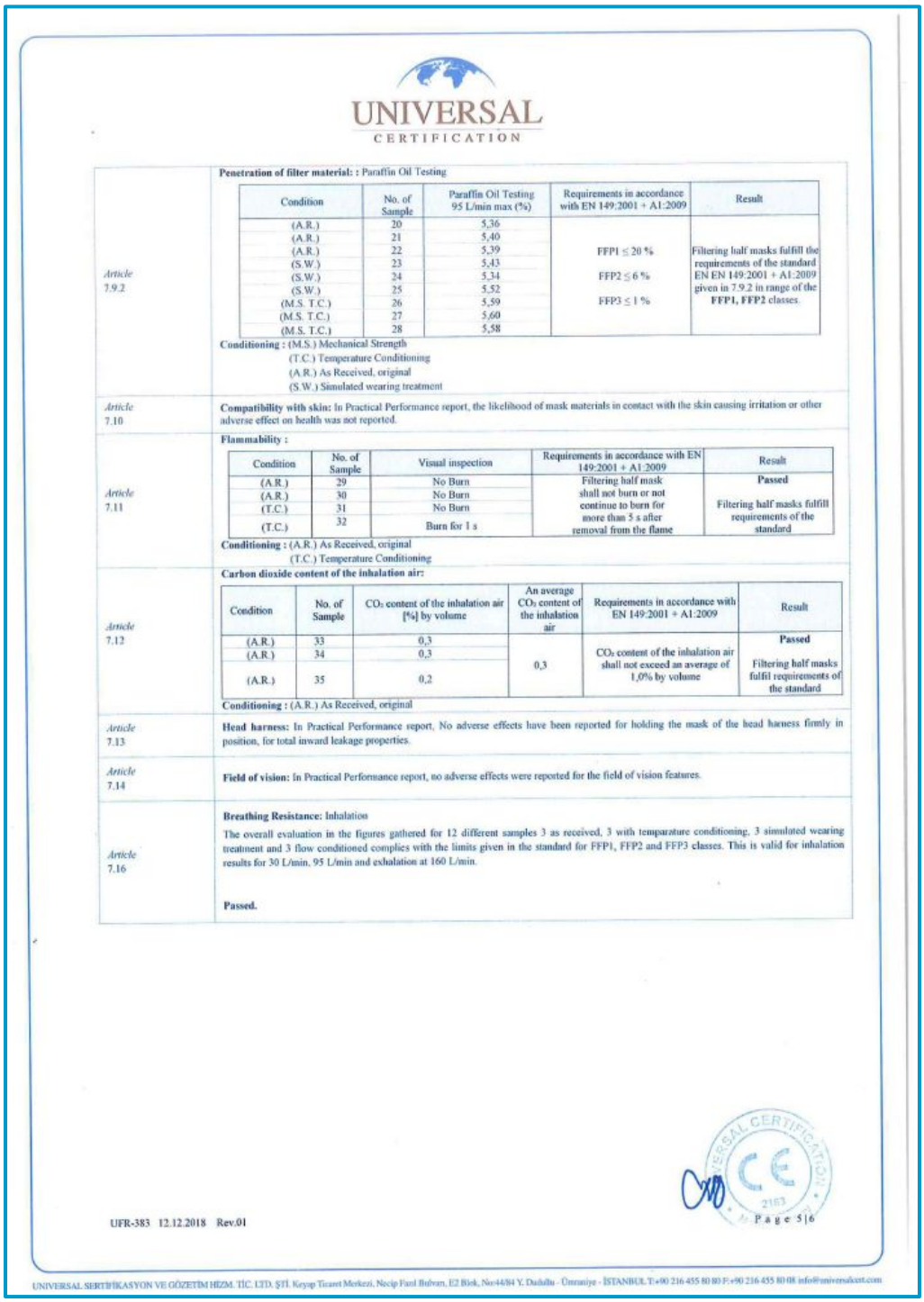

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Article 7.9.2

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.

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Mascarilla FFP2

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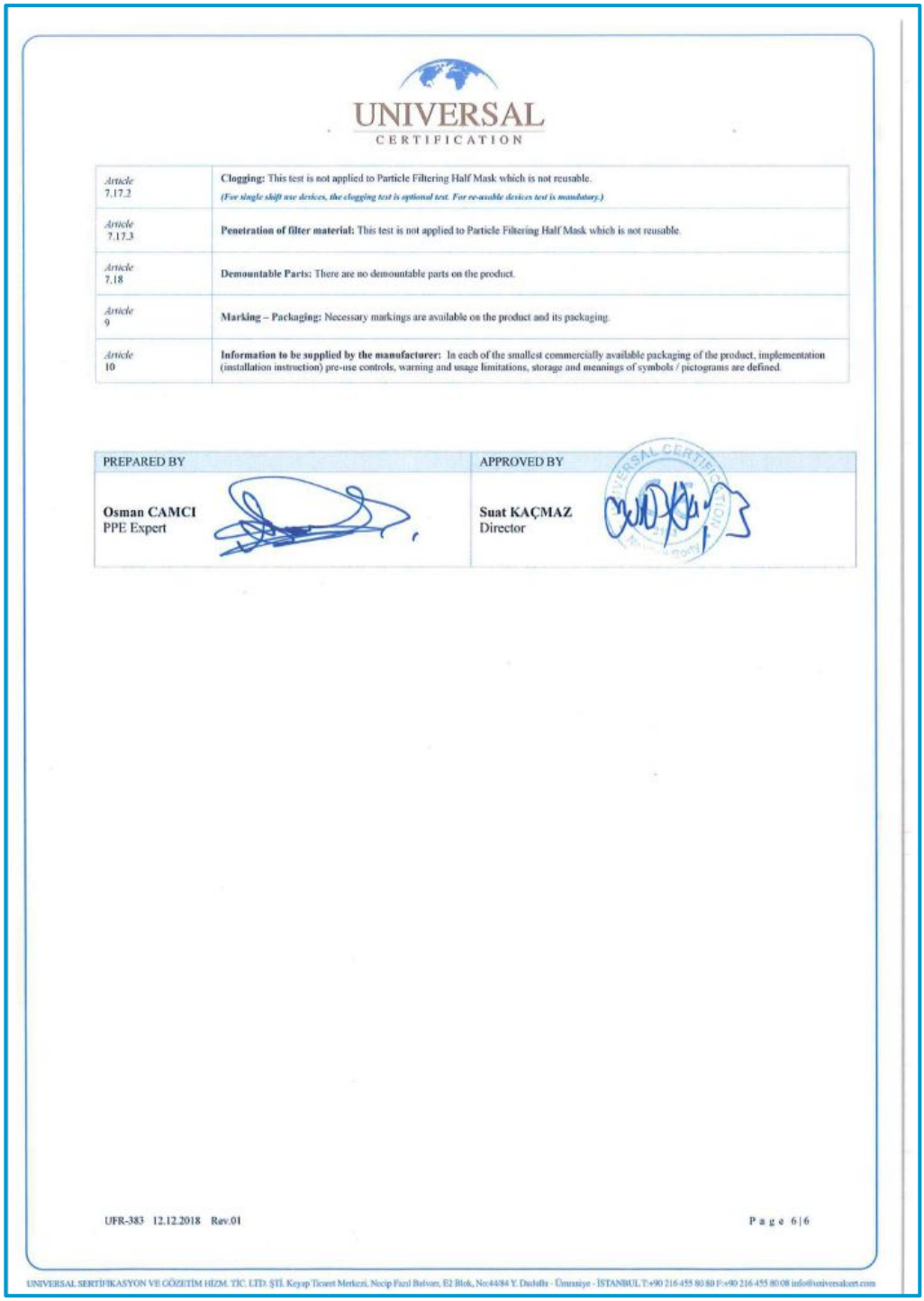
Certificado CE



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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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Mascarilla FFP2

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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