



# DOCUMENTATION

## MASK ULTRA PROTECTION FFP2

MASCARILLA ULTRA PROTECCIÓN FFP2

MASQUE FFP2 ULTRA PROTECTION FFP2

MASCHERINA PROTEZIONE ULTRA FFP2



MASTER BOX: 1000 pcs



CV-41

ITEM: [REDACTED]

DESCRIPTION: NAAMIO

MATERIAL:

3 PLY (40% non woven, 38% Meltblown, 22% algodón).

QUANTITY: 1.000

G.W

N.W

CNT SIZE

BATCH NUMBER:

PRODUCTION DATE:

VALIDITY:

产品名称: FFP2防护口罩(非医用)  
 执行标准: EN149:2001+A1:2009  
 生产厂商: 深圳市和正实业发展有限公司  
 生产地址: 深圳市龙华区观湖街道松元厦社区环观中路172号兆业厂房601

MADE IN P.R.C.

BOX: 25 pcs

**FFP2**  
Personal Protective Equipment  
Equipo de Protección Individual (EPI)

CE 2163 | EN 149:2001+A1:2009  
FFP2 NR  
Filtration Efficiency ≥95%



CV-41 **MASCARILLA ULTRA PROTECCIÓN FFP2**  
Comfortable protection against infection / Protección cómoda contra infecciones.

**MASCARILLA ULTRA PROTECCIÓN FFP2**  
FFP2 Personal Protective Equipment  
Equipo de Protección Individual (EPI)

**Instructions:**



**Step for usage:**

1. Open the foldable mask.
2. Make the nose bridge bar on the up side.
3. Put the strap onto the ear.
4. Adjust the soft bar to fit the nose.
5. Make sure you can breathe well and readjust if necessary.

**INSTRUCCIONES DE USO:**

1. Abra la máscara plegable.
2. Ajuste la máscara con la parte superior de la nariz.
3. Ajuste las cintas elásticas por detrás de las orejas.
4. Amolde la barra nasal a la parte superior de la nariz.
5. Asegúrese de poder respirar bien y ajuste si es necesario.

**WARNING:**

1. This mask marked "NR" is for single use only.
2. This mask helps protect against certain particulate contaminants but does not completely eliminate exposure to the risk of contracting disease or infection.
3. Change the mask immediately if breathing becomes difficult or the mask becomes damaged or distorted.

**ATENCIÓN:**

1. Esta máscara "NR" es recomendada para un sólo uso.
2. Esta máscara ayuda a proteger contra ciertas partículas contaminantes, pero no elimina por completo la exposición al riesgo de contraer enfermedades o infecciones.
3. Cambie la máscara inmediatamente si la respiración se vuelve difícil o si la máscara se daña o se distorsiona.

**FFP2**  
Personal Protective Equipment  
Equipo de Protección Individual (EPI)

CE 2163 | EN 149:2001+A1:2009  
FFP2 NR  
Filtration Efficiency ≥95%



CV-41 **MASCARILLA ULTRA PROTECCIÓN FFP2**  
Comfortable protection against infection / Protección cómoda contra infecciones.

**MASCARILLA ULTRA PROTECCIÓN FFP2**  
FFP2 Filtrating half mask  
Standard: 2016/425 Personal Protective Equipment (EPI)  
EN 149:2001+A1:2009

Organismo notificador: CE 2163  
Marca: DRHZ  
Referencia del producto: HZ96  
Material: 48% No-woven, 31% Meltblown, 22% algodón  
Cantidad por caja: 25 piezas

Fecha de producción:  
Lote:  
Plazo de validez:  
Condiciones de almacenamiento:  
Temperatura de -20°C a 40°C, humedad relativa menos del 60%.  
Se debe garantizar que las cajas estén cerradas, no estén dañadas, no estén contaminadas, no se vean afectadas por la humedad, preste atención a la prevención de incendios, evite que las cajas se mojen y la exposición de las mismas al sol.

Product description: FFP2 Filtrating half mask  
Standard: 2016/425 Personal Protective Equipment (EPI)  
EN 149:2001+A1:2009  
Notified body: CE 2163  
Brandname: DRHZ  
Model: HZ96  
Material: Non-woven fabric 47%, meltblown fabric 31%, hot air cotton 22%  
Production quantity: 25 pieces/box

Production Date:  
Production Batch:  
Expiration date:  
Storage conditions:  
Temperature -20°C to 40°C, relative humidity less than 60%.  
Products in storage and transport should be guaranteed to be sealed, not damaged, not contaminated, not affected with damp, pay attention to fire prevention, rain-proof, acid-proof, alkali-proof, avoid hard light.

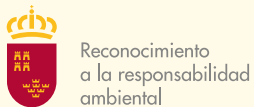
产品信息: FFP2型半罩(半面罩)  
执行标准: EN 149:2001+A1:2009  
生产厂商: 深圳市龙岗区宝龙街道宝龙社区坪地岗172号奥达工厂(0401)

MADE IN P.R.C.

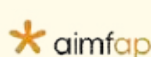
BAG: 1 pc



Colaboramos con



Asociaciones y Entidades a las que pertenecemos



**EU DECLARE OF THE CONFORMITY**

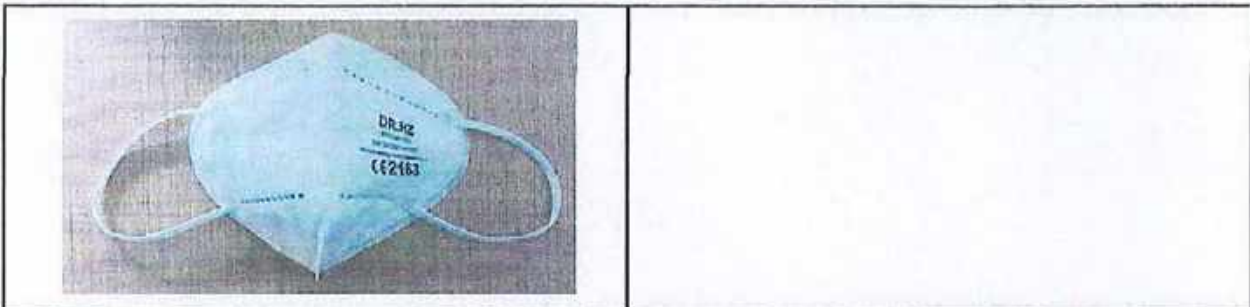
We

Company name:	[REDACTED]
Postal address:	[REDACTED]
Postcode:	[REDACTED]
City:	[REDACTED]

Declare that the DoC is issued under our sole responsibility and belongs to the following products:

Apparatus model/Product:	[REDACTED]
Type:	Filtering half mask

Object of the declaration(identification of apparatus allowing traceability. It may include a colour image of sufficient clarity where necessary for the identification of the appearance)



The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:

**Personal protective equipment Regulation(EU)2016/425**

The following harmonised standards and technical specifications have been applied:

Title, Date of standards/specification:

**EN149:2001 +A1 :2009**

Notified body (where applicable)	4 digit notified body number
UNIVERSAL CERTIFICATION AND SURVEILLANCE SERVICE TRADE LTD. CO.	[REDACTED]
Certificate Number:	[REDACTED]
Technical report numbered:	[REDACTED]

Signed for and on behalf of

Guangdong,China

Sep.07.2020

Place of issue

Date of issue



Name,function,signature General Manager



**UNIVERSAL**  
CERTIFICATION

## EU TYPE EXAMINATION CERTIFICATE

Certificate No: [REDACTED]

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

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

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 02/09/2020 and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.



Suat KACMAZ  
UNIVERSAL CERTIFICATION  
Director

## CERTIFICATE OF CONFORMANCE

Certificate No: [REDACTED]

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

[REDACTED]

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
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

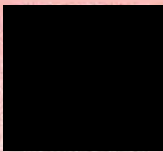
Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- 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 29/09/2020 and will be valid for one year, until 28/09/2021 if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.



Suat KACMAZ  
UNIVERSAL CERTIFICATION  
Director



**TECHNICAL ASSESSMENT REPORT**

**REPORT DATE / NO:** [REDACTED]

**Manufacturer:** [REDACTED]  
[REDACTED]  
[REDACTED]

This report is for the, given above, manufacturer prepared according to the test results obtained from Jiangsu Guojian Testing Technology Co., Ltd. accredited by CNAS (China National Accreditation Service), signatory to ILAC MRA, with number [REDACTED] for the product identified below, dated 22.06.2020 with Serial Id [REDACTED] based on EN 149: 2001 + A1: 2009 standard and the technical file dated 28 August, 2020 Version 01 provided by the manufacturer.

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 Personal 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:** [REDACTED]

**Classification:** FFP2 NR

**Brandname:** [REDACTED]



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

**1.1. Design principles**

**1.1.1. Ergonomics**

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

Any impediment 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 address of 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 question;
- 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 deadline or period of obsolescence of PPE or 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 in accordance with Article 5(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



## 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 remain perfectly legible throughout the foreseeable useful 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 all or part of the necessary marking to be affixed, the relevant information must be mentioned on the packing and in the manufacturer's notes.

## 3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

### 3.10.1. Respiratory protection

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

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

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

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

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

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





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**

<i>Article</i> 5	<p><b>Classification: Particle Filtering Half Mask</b></p> <p>The mask subject to evaluation based on the test results and technical file provided by the manufacturer is classified as: <b>Filtering Efficiency and Maximum Total Inward Leakage: Classified as FFP2</b> Mask is classified for single shift use, NR</p>																																					
<i>Article</i> 7.4	<p><b>Packing:</b> Particle filtering half masks are packaged to protect them from contamination before use and with cardboard boxes to prevent mechanical damage. The packaging design and the product is considered to withstand the foreseeable conditions of use based on the visual inspection results given in the test report.</p>																																					
<i>Article</i> 7.5	<p><b>Material:</b> Materials used in particle filtering half masks, according to the simulated wearing treatment and temperature conditioning results; It is understood it withstands handling and wear over the period for which the particle filtering half mask is designed to be used, it suffered mechanical failure of the facepiece or straps, any material from the filter media released by the air flow through the filter has not constitute a hazard or nuisance for the wearer. The manufacturer declares that the materials used in manufacturing of the mask does not have an adverse affect to the health and safety of users.</p> <p>Based on the test results, the masks did not collapse when subject to simulated wearing and temperature conditioning. No nuisance situation is reported during the practical performance tests by human subjects.</p>																																					
<i>Article</i> 7.6	<p><b>Cleaning and Disinfection:</b> Particle filtering half mask is not designed to be as re-usable. No cleaning or disinfection procedure provided by the manufacturer.</p>																																					
<i>Article</i> 7.7	<p><b>Practical Performance:</b></p> <p>The test report indicates that the human subjects did not face any difficulty in performing the exercises while they were wearred by the sample masks, in walking test or work simulation tests. The wearers did not report any failure by means of head harness / straps/ earloops comfort, security of fastenings and field of vision. Also no imperfections reported during total inward tests about the comfort, field of vision and fastening issues.</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Assessed Elements</th> <th>Positive</th> <th>Negative</th> <th>Requirements in accordance with EN 149:2001 + A1:2009 and Result:</th> </tr> </thead> <tbody> <tr> <td>2.Head harness comfort</td> <td style="text-align: center;">2</td> <td style="text-align: center;">0</td> <td rowspan="3" style="text-align: center;">Positive results are obtained from the test subjects No Imperfections</td> </tr> <tr> <td>3.Security of fastenings</td> <td style="text-align: center;">2</td> <td style="text-align: center;">0</td> </tr> <tr> <td>5.Field of vision</td> <td style="text-align: center;">2</td> <td style="text-align: center;">0</td> </tr> </tbody> </table> <p>Conditioning: (A.R.) As Received, original</p>	Assessed Elements	Positive	Negative	Requirements in accordance with EN 149:2001 + A1:2009 and Result:	2.Head harness comfort	2	0	Positive results are obtained from the test subjects No Imperfections	3.Security of fastenings	2	0	5.Field of vision	2	0																							
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<i>Article</i> 7.8	<p><b>Finish of Parts:</b> Particle filtering half masks, which are likely to come into contact with the user, do not have sharp edges and do not contain burrs.</p>																																					
<i>Article</i> 7.9.1	<p><b>Total Inward Leakage:</b></p> <p>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 exercises defined in the standard. The samples used in the test are subjected to the conditioning required in the standard as temperature conditioning and as received. The face dimensions of the subjects are also reported. The measurement details for each subject and for each exercise are available in the test report.</p> <p>It was reported that: All 50 exercise measurement results are smaller or equal to 11%, the values varies between 2.4% and 6.1%. All 10 individual's arithmetic mean is smaller or equal to 8%, the values varies between 3.5% and 5.0%.</p> <p style="text-align: center;">According to the reported results, the product meets the limits for FFP2 classification.</p>																																					
<i>Article</i> 7.9.2	<p><b>Penetration of filter material: Sodium Chloride Testing</b></p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Condition</th> <th>No. of Sample</th> <th>Sodium Chloride Testing 95 L/min max (%)</th> <th>Requirements in accordance with EN 149:2001 + A1:2009</th> <th>Result</th> </tr> </thead> <tbody> <tr> <td>(A.R.)</td> <td style="text-align: center;">-</td> <td style="text-align: center;">0.1</td> <td rowspan="3" style="text-align: center;">FFP1 ≤ 20 %</td> <td rowspan="9" style="text-align: center;">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 and FFP3 classes.</td> </tr> <tr> <td>(A.R.)</td> <td style="text-align: center;">-</td> <td style="text-align: center;">0.1</td> </tr> <tr> <td>(A.R.)</td> <td style="text-align: center;">-</td> <td style="text-align: center;">0.2</td> </tr> <tr> <td>(S.W.)</td> <td style="text-align: center;">-</td> <td style="text-align: center;">0.1</td> <td rowspan="2" style="text-align: center;">FFP2 ≤ 6 %</td> </tr> <tr> <td>(S.W.)</td> <td style="text-align: center;">-</td> <td style="text-align: center;">0.2</td> </tr> <tr> <td>(S.W.)</td> <td style="text-align: center;">-</td> <td style="text-align: center;">0.1</td> <td rowspan="3" style="text-align: center;">FFP3 ≤ 1 %</td> </tr> <tr> <td>(M.S. T.C.)</td> <td style="text-align: center;">-</td> <td style="text-align: center;">0.2</td> </tr> <tr> <td>(M.S. T.C.)</td> <td style="text-align: center;">-</td> <td style="text-align: center;">0.3</td> </tr> <tr> <td>(M.S. T.C.)</td> <td style="text-align: center;">-</td> <td style="text-align: center;">0.2</td> <td></td> </tr> </tbody> </table> <p>Conditioning: (M.S.) Mechanical Strength (T.C.) Temperature Conditioning (A.R.) As Received, original (S.W.) Simulated wearing treatment</p> <p style="text-align: right;">95 L/min = 1,6 dm<sup>3</sup>.sn<sup>-1</sup></p>	Condition	No. of Sample	Sodium Chloride Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result	(A.R.)	-	0.1	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 and FFP3 classes.	(A.R.)	-	0.1	(A.R.)	-	0.2	(S.W.)	-	0.1	FFP2 ≤ 6 %	(S.W.)	-	0.2	(S.W.)	-	0.1	FFP3 ≤ 1 %	(M.S. T.C.)	-	0.2	(M.S. T.C.)	-	0.3	(M.S. T.C.)	-	0.2	
Condition	No. of Sample	Sodium Chloride Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result																																		
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Article 7.9.2	<b>Penetration of filter material: Paraffin Oil Testing</b>					
	Condition	No. of Sample	Paraffin Oil Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result	
	(A.R.)	-	0.2	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 and FFP3 classes.	
	(A.R.)	-	0.3			
	(A.R.)	-	0.3			
	(S.W.)	-	0.3			
	(S.W.)	-	0.3			
	(S.W.)	-	0.2			
	(M.S. T.C.)	-	0.8			
	(M.S. T.C.)	-	0.7			
	(M.S. T.C.)	-	0.9			
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	<b>Flammability:</b>					
	Condition	No. of Sample	Visual inspection	Requirements in accordance with EN 149:2001 + A1:2009	Result	
	(A.R.)	-	Burn for 0.1s	Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame	Passed  Filtering half masks fulfill requirements of the standard	
	(A.R.)	-	Burn for 0.1s			
	(T.C.)	-	Burn for 0.1s			
	(T.C.)	-	Burn for 0.1s			
Conditioning: (A.R.) As Received, original (T.C.) Temperature Conditioning						
Article 7.12	<b>Carbon dioxide content of the inhalation air:</b>					
	Condition	No. of Sample	CO <sub>2</sub> content of the inhalation air [%] by volume	An average CO <sub>2</sub> content of the inhalation air	Requirements in accordance with EN 149:2001 + A1:2009	Result
	(A.R.)	-	0.7057	0.70[%]	CO <sub>2</sub> 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.)	-	0.7015			
	(A.R.)	-	0.7027			
Conditioning: (A.R.) As Received, original						
Article 7.13	Head harness: In Practical Performance and TIL test reports no adverse effects have been reported for donning and remove of the mask also the results of these tests indicates that the ear loops / head harness are capable of holding the mask firmly enough.					
Article 7.14	Field of vision: In Practical Performance report, no adverse effects were reported for the field of vision availability when the mask is worn.					
Article 7.15	Exhalation Valve(s): The model under inspection have no valves.					
Article 7.16	<b>Breathing Resistance: Inhalation</b>					
	The overall evaluation in the figures gathered for 9 different samples 3 as received, 3 with temperature conditioning and 3 simulated wearing treatment complies with the limits given in the standard for FFP1, FFP2 and FFP3 classes. This is valid for inhalation results for 30 L/min, 95 L/min and exhalation at 160 L/min.					
Passed.						

Article 7.17	<b>Clogging:</b> This test is not applied to Particle Filtering Half Mask which is not reusable. (For single shift use devices, the clogging test is optional test. For re-usable devices test is mandatory.)
Article 7.18	<b>Demountable Parts:</b> There are no demountable parts on the product.
Article 8	<b>Testing:</b> All tests conducted according to Clause 8 of this standard is available in the test report and are evaluated in this report for qualification and classification of the mask.
Article 9	<b>Marking – Packaging:</b> Necessary markings are available on the product package (box). The name and trademark of the manufacturer is clearly visible. The type of the mask and the classification including the status of re-usability, the reference to EN 149:2001+A1:2009 standard, the year of end of shelf life, using and storage instructions and pictograms and CE mark are available on the product package. The above evaluation is based on the technical document for packaging and marking, for box design. Verified on the Annex 9.1 of the technical file.  The technical documentation for mask design (drawing) also evaluated for marking requirements, drawing HZ96. The mask template (drawing) indicates that the mask will carry information about the name and the brandname (Shenzhen Hezheng Industrial Development Co., Ltd. / Dr.HZ) of the manufacturer, type of mask, the reference to EN 149+A1:2009 standard and classification including the re-usability of the mask. The manufacturer also printed CE mark with our Notified Body number. The mask do not have sub-assemblies. Even the tested samples by the laboratory do not carry necessary marking information as stated in the technical documentation, the manufacturer shall follow marking instructions for serial production. Model HZ96 drawing exists in the technical file of the manufacturer, Annex 6 of technical file.
Article 10	<b>Information to be supplied by the manufacturer:</b> In each of the smallest commercially available packaging of the product, implementation (installation instructions) pre-use controls, warning and usage limitations, storage and meanings of symbols / pictograms are defined. User instruction document in the technical file found to be appropriate, Annex 8. The manufacturer shall include this documented user information text in every smallest commercially available package.

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