Eindbeoordelingsformulier - FFP Mondmaskers (LOT-nummers)

Datum	23-6-20.
Lotnummer	1803 -
Leverancier/LCH-nummer	
Productnaam of naam fabrikant	KN95 Protective Mask.
Productiedatum	
Type mondmasker (volgens de fabrikant)	KN95.

Q1 Particle Penetration 0,3	**Percentage**		**Type P1/P2/P3**
Masker 1	99%	98%	
Masker 2	100%	100%	
Masker 3	99%		

Q2 Fittest	**Zonder clip**		**Met clip**	
Testpersoon 1	7,6	11	42	31
Testpersoon 2	10	7,9	28	39
Testpersoon 3	<10	<10	40	12
FFP2	☐ FAIL ☐ PASS			

Q3 en Q4	**+**	**+/-**	**-**
Oordeel RIVM			—
Oordeel AH/TOXI			—

Artikelnummer VWS	**Quality Check**
☐ 957 (FFP1) ☐ 958 (FFP2) ☒ 971 (KN95)	☐ Goedgekeurd ☒ Afkeur

Algemene bevindingen:

Logistiek	**Aankruisen**	**Classificatie**	**Clip (Ja/Nee)**	**Specs.**	
				PFE	**FIT**
Mand 1		Goedkeur: FFP2		>94%	>100
Mand 2		Goedkeur: FFP2 met instructie over FIT		>94%	33<FIT<100
Mand 3		Afkeur: FFP1, filter van mindere kwaliteit*		80%<PFE<94%	>100
Mand 4		Afkeur: FFP1, buiten acute zorg, met instructie over FIT (Q57)		80%<PFE<94%	33<FIT<100
Mand 5	X	Afkeur: Alleen uitleveren bij hoge nood	ja	>94%	<33
Mand 6		Afkeur: Alleen uitleveren bij hoge nood		80%<PFE<94%	<33
Mand 7		Afkeur: Niet gebruiken		< 80	Ongeacht fit

* ingekocht FFP1 in mand 3 boeken als goedkeur

Checklist prestatiecontrole adembeschermingsmaskers

Inkoopnummer		**LOT-nummer**	1803
Datum uitvoering check	23-6-20		
Leveringsdatum			
Leverancier			
Productnaam of naam fabrikant	KNGS Protective Mask Hioria con.		
Productiedatum			
Naam	5.1.2e		
Functie			
Besproken met RIVM			

Advies:

Type masker bij uitgifte:

Werkwijze:
RIVM voert de "administratieve" controle uit met betrekking tot notified bodies, certificaten en Declarations of Conformities. De arbeidshygiënisten beoordelen opdruk binnendoos, verpakking masker op onregelmatigheden met behulp van deze checklist. Het masker zelf wordt gecontroleerd op aantal lagen, kwaliteit, bevestiging van elastieken en fit op het gezicht. Vervolgens wordt een gezamenlijk advies gegeven over onder welke categorie dit masker zal worden uitgegeven naar de ziekenhuizen.

Administratief (wordt ingevuld door RIVM)

Technical data sheet aanwezig?	☒ Ja	☐ Nee
Garantiecertificaat aanwezig?	☒ Ja	☐ Nee
Declaration of conformity aanwezig?	☐ Ja	☒ Nee
Oordeel van RIVM	5.1.2i Toelichting	

Prestatie levering

Oordeel arbeidshygienisten	- EN ug cerificaat → op doos staat dit niet. - Fit niet optimaal.

Bijzonderheden:

	VERPAKKING OM HET INDIVUELE MASKER		
1	Zit er verpakking om het masker?	☑ Ja	☐ Nee
	Zo ja:		
2	Hoe is de verpakking te openen?	☑ Gemakkelijk ☐ Lastig ☐ Moeilijk	
3	Correspondeert de verpakking met de informatie op de binnendoos?	☒ Ja ☐ Nee, het volgende wijkt af:	

Bijzonderheden:

	DE FIT VAN HET MASKER OP HET GEZICHT	
1	Hoe past het masker op het gezicht?	☐ Goed ☒ Ruimte bij de kin ☒ Ruimte bij neusstuk na aandrukken ☐ Slechte aansluiting bij wangen ☐
2	Waar ontsnapt lucht bij de leaktest	☐ Niet ☒ Neus ☒ Kin ☐ Zijkant ☐ N.v.t. (Chirurgisch)
3	Kan het masker met de touwtjes en elastieken strakker op het gezicht worden getrokken?	☐ Ja ☒ Nee ☐ N.v.t.
4	Wat gebeurt er als het gezicht beweegt?	☐ Masker blijft op zijn plek ☒ Masker verschuift ☐
5	Behoudt de neusklem zijn vorm gedurende circa 1 min?	☒ Ja ☐ Nee ☐ N.v.t.
6	Chirurgisch masker: Wat is de hoogte van het masker wanneer deze uitgevouwen is?	nvt
7	Chirurgisch masker: wat is de lengte van de neusklem?	nvt

	Bij een chirurgisch masker		
Doos	**Materiaal neusbeugel**	**Breedte neusbeugel**	**Lengte van het uitgeklapte masker**
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			

Bijzonderheden:

1120388

(1)

Particle Penetration by Kalibra

Datum	23-06-2020
Inkoopnummer	304634
LOT/X-nummer	1803-A

Q1 Particle Penetration	Gemiddelde rendement ≥ 0,3	Pass or Fail t.o.v. P1/P2/P3
Masker 1 Pass 1	99%	Pass P3
Masker 2 Pass 2	100%	" P3
Masker 3 Pass 3	99%	" P3

Ademweerstand:

	Gemeten (< Pa)	Eis (< Pa)	Conclusie
Masker 1	115	< 240 Pa	Pass
Masker 2	112		Pass
Masker 3	114		Pass.

Eindoordeel ≥ 0,3:

Beoordeling op basis van masker met het laagste filterrendement.

- ☐ fail
- ☐ voldoet P1
- ☒ voldoet aan P2 → Zie (2). maskers 4
- ☐ voldoet aan P3

1120388

2

Particle Penetration by Kalibra

Datum	23-06-2020
Inkoopnummer	304634
LOT/X-nummer	1803-B

Q1 Particle Penetration	Gemiddelde rendement ≥ 0,3	Pass or Fail t.o.v. P1/P2/P3
Masker ~~1~~ ~~2~~ 4 Pass 4	98%	Pass P2
Masker ~~3~~ ~~4~~ 5 Pass 5.	100%.	Pass P3
Masker ~~5~~		

Ademweerstand:

	Gemeten (< Pa)	Eis (< Pa)	Conclusie
Masker 1	87	< 240 Pa	
Masker 2	114		
Masker 3			

Eindoordeel ≥ 0,3:

Beoordeling op basis van masker met het laagste filterrendement.

- ☐ fail
- ☐ voldoet P1
- ☑ voldoet aan P2
- ☐ voldoet aan P3

Fittest by RIVM

Datum	23-06-2020
LOT/X-nummer	1803

Fit factor real time test < 10	☐ Ja, test alleen met Clip	☑ Nee, test zonder en met clip of kam

	Zonder clip of kam		Met clip of kam	
Tester:	Opmerkingen	Score	Opmerkingen	Score
1 [redacted] (1)	doos 1	7,6.		42
2 5.1.2e (2)	te Gs	10	Fit raakt kwijt..	28
3 3	veel lucht	K10		40
4.				
Algemeen: (ruim, krap, etc)				
Verschuift bij Up & Down/Bending?		Ja		JA
			Is één clip voldoende?	JA.

Extra opmerkingen (eventueel met pijlen waar lekkage is)

Type FFP Masker	
Fit test (FAIL of PASS)	pass

Fittest by RIVM

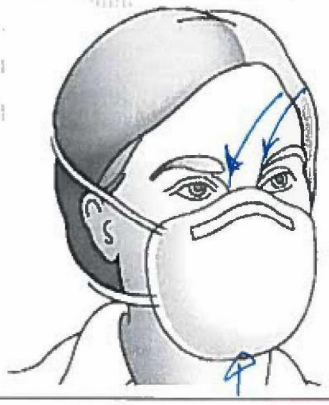
Datum	23-6-2020
LOT/X-nummer	1803

Fit factor real time test < 10	☐ Ja, test alleen met Clip	☐ Nee, test zonder en met clip of kam

doos

	Zonder clip of kam		Met clip of kam	
Tester:	Opmerkingen	Score	Opmerkingen	Score
1. [redacted] (4)	Fit sluit niet goed	11		21
2. [redacted]	doos 5	7,9		39
3. [redacted] (6)	reel/ime	<10		12
4.				
Algemeen: (ruim, krap, etc)				
Verschuift bij Up & Down/Bending?		ja		ja (~~nee~~)
			Is één clip voldoende?	JA

Extra opmerkingen (eventueel met pijlen waar lekkage is)



Type FFP Masker	
Fit test (FAIL of PASS)	Pass

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Inboekrapport VWS

Naam Ontvanger: _____ Datum: 18-6-20

Aantal inkooporder/pakbon _____ Lotnummer 1803A

Aantal pallets	~~20~~ 21 + 9 = 30 (21)
Totaal stuks	~~345.600~~ 362.880 + 144.720 = 507.600
Aantal samples	180
Totaal aantal na samples	~~345.420~~ 362.700

Aantal per pallet	17280
Aantal per doos	1080
Aantal per verpakkingseenheid	30

Aantal komt overeen met inkooporder/pakbon JA / NEE

Zo niet **Telling bevestigd door** Naam: _____

Paraaf: _____

Artikelnummer: 950 Inkooporder nummer 304634

LCH-nummer VWS kenmerk 3057-23164-06

Kwaliteitscontrole RIVM JA / NEE

GOEDGEKEURD / AFGEKEURD

Bijzonderheden:

Locatie: 22 - 085 - 4 Ingeboekt door:

6/M → 22-143-4

Inboekrapport VWS

Naam Ontvanger: ..... Datum: 18-6-20

Aantal inkooporder/pakbon ..... Lotnummer 1803 B

Aantal pallets	9
Totaal stuks	144720
Aantal samples	—
Totaal aantal na samples	—

Aantal per pallet	17280
Aantal per doos	1080
Aantal per verpakkingseenheid	30

Aantal komt overeen met inkooporder/pakbon **JA / NEE**

Zo niet **Telling bevestigd door** Naam: .....

Paraaf: .....

Artikelnummer: ..... Inkooporder nummer .....

LCH-nummer VWS-kenmerk-3057-23164-06

Kwaliteitscontrole RIVM **JA / NEE**

GOEDGEKEURD / AFGEKEURD

Bijzonderheden:

Locatie: 22 - 163 - 02 ingeboekt door:

EM 22-185-02

1120388

LETTRE DE VOITURE - DOCUMENT DE TRANSPORT-VRACHTBRIEF-VERVOERSDOCUMENT-FRACHBRIEF

1 Shipper / Absender / Afzender 5.1.2i Heerhugowaard The Netherlands	CMR AVC - 2002 NL 216932
2 Destinataire / Empfanger Centraal Boekhuis Laanakkerweg 14 345444	16 Transporter 5.1.2i
3 Delivery Place, Country / Auslieferungsort Vianen / 4131PB	17 Following Transporters Schiphol Express
4 Receipts Place and Date / Ort und Tag Ubernahme Schiphol , 17-6-2020	18 Vorbehalt und Bemerkungen des Fahrers
5 Documents annexes / Bijgevoegde Documenten MAWB nr 784-13216932	

6 Omschrijving	7 Aantal	8 Verpakking	9 Soort	10 Statist	11 Weight	12 Vol.
MASK (220crt = 237.600 MASK) 5.1.2b			EURO PALLETS		1995kg	
VWS KENMERK: 3057-23164						
*** Status "C" ****						

13 Opmerkingen	19 Speciale Overeenkomst	Afzender	Geldsoort	Ontvanger
DELIVERY 18JUN. I 5.1.2b EURO'S RETOUR	Vrachtprijs Kortingen Saldo Bijeenkomsten Totaal:			

14 Frankeringsvoorschriften / Prescriptions: FRANCO	
15 Remboursement	20 Besondere afspraken
21 Plaats en Datum opmaken Vrachtbrief : Schiphol , 17 JUN 2020	24 Goed Ontvangen / Plaats
Afzen 5.1.2e Transporter S/E	Date Place 5.1.2e

llets

..... x pallets

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CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163 - PPE - 672

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

GILANIA SRL
Via A.Manzoni 29\a 24024 GANDINO –BG- ITALY
manufactured at
PINGXIANG HUAFU MEDICAL HEALTH MATERIALS CO.,LTD
Building 9,Zone A,Electronic Industrial Park, Anyuan City, Jiangxi, 337000, 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: GILANIA **Model:** GIL001
Filtering half mask
Total Inwards Leakage: Class – FFP2

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 **09 / 05 /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

5.1.2e

UNIVERSAL CERTIFICATION
5.1.2e

Verify the validity with the QR

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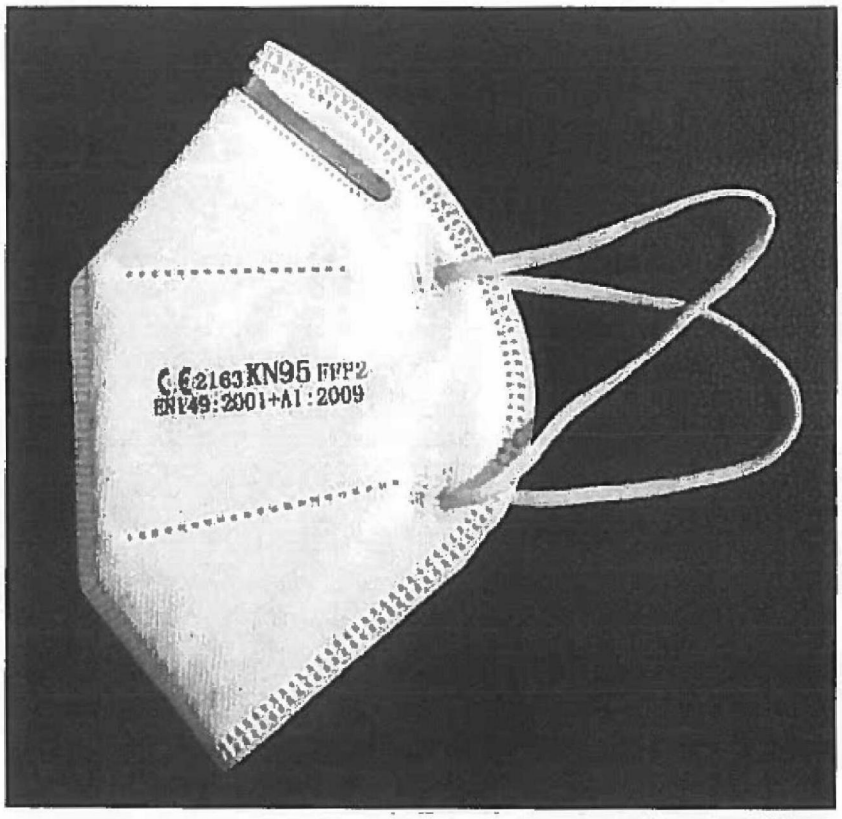
TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO : 08.05.2020 / KKD-2163-672

Client: GILANIA SRL
Centre Address: Via A. Manzoni 29\a - 24024 GANDINO (BG) - ITALY
Manufacturer: PINGXIANG HUAFU MEDICAL HEALTH MATERIALS CO., LTD.
Manufacturing Address: Building 9, Zone A, Electronic industrial park, Anyuan City, Jiangxi, 337000, CHINA

This report is to the above mentioned firm with the NATIONAL PROTECTIVE TESTING LLC firm's 25.04.2020 numbered NPT20040712685 test report and the test results which have been obtained according to the EN 149: 2001 + A1: 2009 standards of the product specified in this report, its relation was evaluated with Essential Requirements of Personel Protective Equipments and the results were found to be appropriate.

This report is an annex and an inseparable part of the EU Type Examination Certificate No. 2163 - PPE - 672 issued to the company. The test results and issued certificate belong only to the tested product. The technical report consists of a total of 7 pages.
Product Description : Particle Filtering Half Mask
Total Inward Leakage: Classification – FFP2
Trademark : GILANIA
Model : GIL.001



5.1.2e

UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Koyup 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

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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 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 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

5.1.2e

UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Kayışdağı Ticaret Merkezi, Necip Fazıl Bulvarı, E2 Blok, No:140/84 Y. Dudullu - Ümraniye - İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

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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 lenk-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.

5.1.2e

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

Assessed Elements	Positive	Negative	Requirements in accordance with EN 149:2001 + A1:2009 and Result
1.The face piece fitting	2	0	Positive results should be obtained from the performance tests related to the implementation under real conditions. No imperfections
2.Head harness comfort	2	0	
3.Security of fastenings	2	0	
4.Speech clearness	2	0	
5.Field of vision	2	0	
6.Materials compatibility with skin	2	0	

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:**

Test Subject	No.of sample	Condition	1.Walk	Head left /right	Head up /down	Speech	2. Walk	Average
1	32	A.R	4,85	5,58	5,83	5,64	4,83	5,35
2	33	A.R	4,87	5,61	5,90	5,69	4,91	5,40
3	34	A.R	4,99	5,69	5,94	5,75	4,95	5,46
4	35	A.R	4,77	5,42	5,61	5,57	4,74	5,22
5	36	A.R	4,81	5,49	5,73	5,66	4,80	5,30
6	16	T.C.	5,35	5,63	5,49	5,61	5,32	5,48
7	17	T.C.	5,29	5,53	5,30	5,27	5,27	5,33
8	18	T.C.	5,41	5,61	5,56	5,58	5,38	5,51
9	19	T.C.	5,32	5,52	5,33	5,35	5,29	5,36
10	20	T.C.	5,20	5,45	5,24	5,30	5,14	5,27
Average			5,09	5,55	5,59	5,54	5,06	5,37
Min			4,77	5,42	5,24	5,27	4,74	5,22
Max			5,41	5,69	5,94	5,69	5,38	5,51

Conditioning : (A.R.) As Received, original — Results P (%) Leakage Value
(T.C.) Temperature conditioning

Results meet with FFP2 requirements

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.)	23	3,91	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 first and second protection class (FFP1, FFP2)
(A.R.)	24	3,85		
(A.R.)	25	3,76		
(S.W.)	1	4,18		
(S.W.)	2	3,96		
(S.W.)	3	4,15		
(M.S. T.C.)	7	4,66		
(M.S. T.C.)	8	4,57		
(M.S. T.C.)	9	4,32		

Conditioning : (M.S.) Mechanical Strength — 95 L/min = 1,6 $dm^3.sn^{-1}$
(T.C.) Temperature Conditioning
(A.R.) As Received, original
(S.W.) Simulated wearing treatment

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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.)	26	4,07		
(A.R.)	27	4,18		
(A.R.)	28	4,13	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 first and second protection class (FFP1, FFP2)
(S.W.)	4	3,95		
(S.W.)	5	3,88	FFP2 ≤ 6 %	
(S.W.)	6	3,86		
(M.S. T.C.)	10	4,05	FFP3 ≤ 1 %	
(M.S. T.C.)	11	4,17		
(M.S. T.C.)	12	3,98		

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.)	32	1,4	Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame	Passed
(A.R.)	33	1,3		
(T.C.)	21	1,2		Filtering half masks fulfill requirements of the standard
(T.C.)	22	1,1		

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.)	41	0,82	0,86	CO_2 content of the inhalation air shall not exceed an average of 1,0% by volume	Passed
(A.R.)	42	0,86			
(A.R.)	43	0,89			Filtering half masks fulfill requirements of the standard

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

Condition	Inhalation Resistance (mbar)					
	No. of Sample	Flow Rate 30 L/min	Requirements in accordance with EN 149:2001 + A1:2009	Flow Rate 95 L/min	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	29	0,4	FFP1 ≤ 0,6 FFP2 ≤ 0,7 FFP3 ≤ 1,0	1,3	FFP1 ≤ 2,1 FFP2 ≤ 2,4 FFP3 ≤ 3,0	Passed
(A.R.)	30	0,5		1,2		
(A.R.)	31	0,5		1,4		
(S.W.)	1	0,5		1,4		
(S.W.)	2	0,5		1,3		
(S.W.)	3	0,6		1,4		
(T.C.)	13	0,6		1,4		
(T.C.)	14	0,5		1,4		
(T.C.)	15	0,5		1,3		

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

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Article 7.16

Breathing Resistance : Exhalation

Condition	No. of Sample	The dummy head position	Exhalation Resistance: Flow Rate 160 L/min	Exhalation Resistance: Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	29	Facing directly	2,0	FFP1 ≤ 3 FFP2 ≤ 3 FFP3 ≤ 3	Passed
		Facing vertically upwards	2,0		
		Facing vertically downwards	2,0		
		Lying on the left side	2,0		
		Lying on the right side	2,0		
(A.R)	30	Facing directly	2,0		
		Facing vertically upwards	2,1		
		Facing vertically downwards	2,1		
		Lying on the left side	2,1		
		Lying on the right side	2,0		

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

Article 7.16

Breathing Resistance : Exhalation

Condition	No. of Sample	The dummy head position	Exhalation Resistance: Flow Rate 160 L/min	Exhalation Resistance: Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	31	Facing directly	2,2	FFP1 ≤ 3 FFP2 ≤ 3 FFP3 ≤ 3	Passed
		Facing vertically upwards	2,1		
		Facing vertically downwards	2,0		
		Lying on the left side	2,2		
		Lying on the right side	2,0		
(S.W)	1	Facing directly	2,2		
		Facing vertically upwards	2,2		
		Facing vertically downwards	2,2		
		Lying on the left side	2,2		
		Lying on the right side	2,0		

Conditioning : (A.R.) As Received, original
(S.W.) Simulated wearing treatment

Article 7.16

Breathing Resistance : Exhalation

Condition	No. of Sample	The dummy head position	Exhalation Resistance: Flow Rate 160 L/min	Exhalation Resistance: Requirements in accordance with EN 149:2001 + A1:2009	Result
(S.W.)	2	Facing directly	2,0	FFP1 ≤ 3 FFP2 ≤ 3 FFP3 ≤ 3	Passed
		Facing vertically upwards	2,2		
		Facing vertically downwards	2,2		
		Lying on the left side	2,2		
		Lying on the right side	2,0		
(S.W)	3	Facing directly	2,0		
		Facing vertically upwards	2,3		
		Facing vertically downwards	2,3		
		Lying on the left side	2,1		
		Lying on the right side	2,2		

Conditioning : (S.W.) Simulated wearing treatment

5.1.2e

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Article 7.16	**Breathing Resistance : Exhalation** **Conditioning :** (T.C.) Temperature Conditioning

Condition	No. of Sample	The dummy head position	Exhalation Resistance: Flow Rate 160 L/min	Exhalation Resistance: Requirements in accordance with EN 149:2001 + A1:2009	Exhalation Resistance: Result
(T.C.)	13	Facing directly	2,1	FFP1 ≤ 3 FFP2 ≤ 3 FFP3 ≤ 3	Passed
		Facing vertically upwards	2,1		
		Facing vertically downwards	2,0		
		Lying on the left side	2,0		
		Lying on the right side	2,0		
(T.C.)	14	Facing directly	2,0		
		Facing vertically upwards	2,1		
		Facing vertically downwards	2,1		
		Lying on the left side	2,2		
		Lying on the right side	2,2		

Article 7.16	**Breathing Resistance : Exhalation** **Conditioning :** (T.C.) Temperature Conditioning

Condition	No. of Sample	The dummy head position	Exhalation Resistance: Flow Rate 160 L/min	Exhalation Resistance: Requirements in accordance with EN 149:2001 + A1:2009	Exhalation Resistance: Result
(T.C.)	15	Facing directly	2,0	FFP1 ≤ 3 FFP2 ≤ 3 FFP3 ≤ 3	Passed
		Facing vertically upwards	2,1		
		Facing vertically downwards	2,0		
		Lying on the left side	2,0		
		Lying on the right side	2,0		

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 manufacturers:** 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
5.1.2e	5.1.2e

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LETTRE DE VOITURE - DOCUMENT DE TRANSPORT-VRACHTBRIEF-VERVOERSDOCUMENT-FRACHBRIEF

1 Shipper / Absender / Afzender 5.1.2i Heerhugowaard The Netherlands 345443	CMR AVC - 2002 NL 788423
2 Destinataire / Empfanger Centraal Boekhuis Laanakkerweg 14	16 Transporter 5.1.2i
3 Delivery Place, Country / Auslieferungsort Vianen / 4131PB	17 Following Transporters Schiphol Express
4 Receipts Place and Date / Ort und Tag Ubernahme Schiphol , 17-6-2020	18 Vorbehalt und Bemerkungen des Fahrers
5 Documents annexes / Bijgevoegde Documenten MAWB nr 784-13788423	

6 Omschrijving	7 Aantal	8 Verpakking	9 Soort	10 Statist	11 Weight	12 Vol.
MASK (250crt = 270.000 MASK)		5.1.2b	EURO PALLETS		2262kg	
VWS KENMERK: 3057-23164						
*** Status "C" ****						

13 Opmerkingen	19 Speciale Overeenkomst	Afzender	Geldsoort	Ontvanger
DELIVERY 18JUN. I				
5.1.2b EURO's RETOUR	Vrachtprijs			
	Kortingen			
	Saldo			
	Bijeenkomsten			
	Totaal:			

14 Frankeringsvoorschriften / Prescriptions:	FRANCO
15 Remboursement	20 Besondere afspraken
21 Plaats en Datum opmaken Vrachtbrief : Schiphol , 17 JUN 2020	24 Goed Ontvangen / Plaats

Afze 5.1.2i

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NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163 - PPE - 672

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

GILANIA SRL
Via A.Manzoni 29\n 24024 GANDINO –BG- ITALY

manufactured at

PINGXIANG HUAFU MEDICAL HEALTH MATERIALS CO.,LTD
Building 9,Zone A,Electronic Industrial Park, Anyuan City, Jiangxi, 337000, 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: GILANIA **Model:** GIL001

Filtering half mask

Total Inwards Leakage: Class – FFP2

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 **09 / 05 /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

5.1.2e

Verify the validity with the QR

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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TECHNICAL ASSESSMENT REPORT

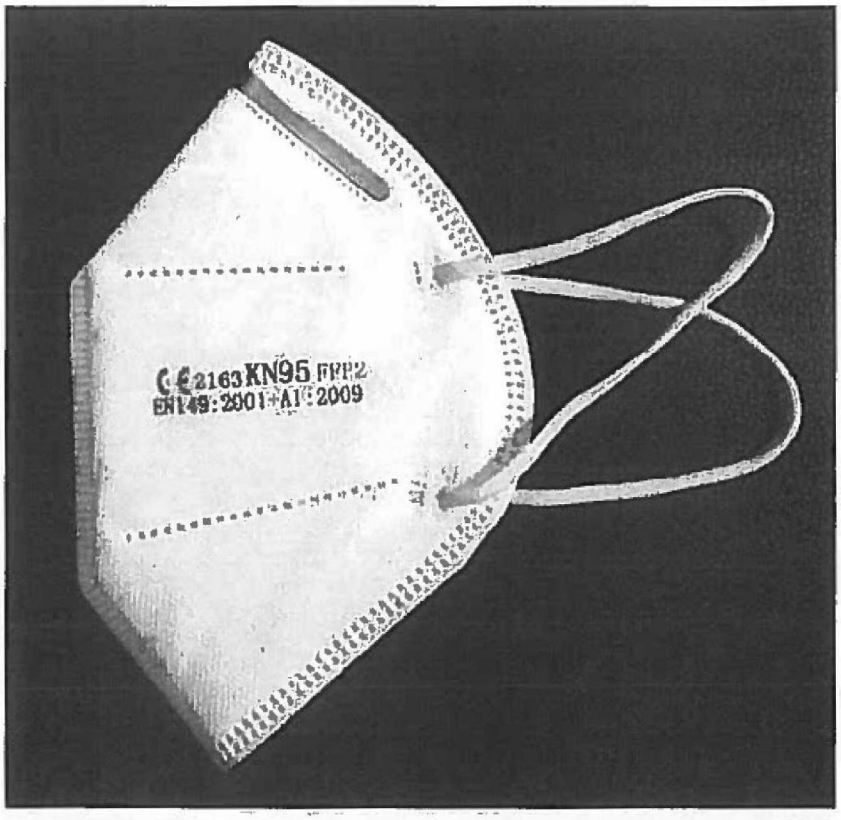
REPORT DATE / NO : 08.05.2020 / KKD-2163-672

Client: GILANIA SRL
Centre Address: Via A. Manzoni 29/i - 24024 GANDINO (BG) - ITALY
Manufacturer: PINGXIANG HUAFU MEDICAL HEALTH MATERIALS CO., LTD.
Manufacturing Address: Building 9, Zone A, Electronic industrial park, Anyuan City, Jiangxi, 337000, CHINA

This report is to the above mentioned firm with the NATIONAL PROTECTIVE TESTING LLC firm's 25.04.2020 numbered NPT20040712685 test report and the test results which have been obtained according to the EN 149: 2001 + A1: 2009 standards of the product specified in this report, its relation was evaluated with Essential Requirements of Personel Protective Equipments and the results were found to be appropriate.

This report is an annex and an inseparable part of the EU Type Examination Certificate No. 2163 - PPE - 672 issued to the company. The test results and issued certificate belong only to the tested product. The technical report consists of a total of 7 pages.

Product Description : Particle Filtering Half Mask
Total Inward Leakage: Classification – FFP2
Trademark : GILANIA
Model : GIL001



5.1.2e

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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 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 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 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 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

[redacted] 5.1.2e

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

Assessed Elements	Positive	Negative	Requirements in accordance with EN 149:2001 + A1:2009 and Result
1.The face piece fitting	2	0	Positive results should be obtained from the performance tests related to the implementation under real conditions. No imperfections
2.Head harness comfort	2	0	
3.Security of fastenings	2	0	
4.Speech clearness	2	0	
5.Field of vision	2	0	
6 Materials compatibility with skin	2	0	

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:**

Test Subject	No.of sample	Condition	1.Walk	Head left /right	Head up /down	Speech	2. Walk	Average
1	32	A.R	4,85	5,58	5,83	5,64	4,83	5,35
2	33	A.R	4,87	5,61	5,90	5,69	4,91	5,40
3	34	A.R	4,99	5,69	5,94	5,75	4,95	5,46
4	35	A.R	4,77	5,42	5,61	5,57	4,74	5,22
5	36	A.R	4,81	5,49	5,73	5,66	4,80	5,30
6	16	T.C.	5,35	5,63	5,49	5,61	5,32	5,48
7	17	T.C.	5,29	5,53	5,30	5,27	5,27	5,33
8	18	T.C.	5,41	5,61	5,56	5,58	5,38	5,51
9	19	T.C.	5,32	5,52	5,33	5,35	5,29	5,36
10	20	T.C.	5,20	5,45	5,24	5,30	5,14	5,27
Average			5,09	5,55	5,59	5,54	5,06	5,37
Min			4,77	5,42	5,24	5,27	4,74	5,22
Max			5,41	5,69	5,94	5,69	5,38	5,51

Conditioning : (A.R.) As Received, original — Results P (%) Leakage Value
(T.C.) Temperature conditioning

Results meet with FFP2 requirements

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.)	23	3,91	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 first and second protection class (FFP1, FFP2)
(A.R.)	24	3,85		
(A.R.)	25	3,76		
(S.W.)	1	4,18		
(S.W.)	2	3,96		
(S.W.)	3	4,15		
(M.S. T.C.)	7	4,66		
(M.S. T.C.)	8	4,57		
(M.S. T.C.)	9	4,32		

Conditioning : (M.S.) Mechanical Strength — 95 L/min = 1,6 $dm^3.sn^{-1}$
(T.C.) Temperature Conditioning
(A.R.) As Received, original
(S.W.) Simulated wearing treatment

5.1.2e

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Article 7.16

Breathing Resistance : Exhalation

Condition	No. of Sample	The dummy head position	Exhalation Resistance: Flow Rate 160 L/min	Exhalation Resistance: Requirements in accordance with EN 149:2001 + A1:2009	Result
(T.C.)	13	Facing directly	2,1	FFP1 ≤ 3 FFP2 ≤ 3 FFP3 ≤ 3	Passed
		Facing vertically upwards	2,1		
		Facing vertically downwards	2,0		
		Lying on the left side	2,0		
		Lying on the right side	2,0		
(T.C.)	14	Facing directly	2,0		
		Facing vertically upwards	2,1		
		Facing vertically downwards	2,1		
		Lying on the left side	2,2		
		Lying on the right side	2,2		

Conditioning : (T.C.) Temperature Conditioning

Article 7.16

Breathing Resistance : Exhalation

Condition	No. of Sample	The dummy head position	Exhalation Resistance: Flow Rate 160 L/min	Exhalation Resistance: Requirements in accordance with EN 149:2001 + A1:2009	Result
(T.C.)	15	Facing directly	2,0	FFP1 ≤ 3 FFP2 ≤ 3 FFP3 ≤ 3	Passed
		Facing vertically upwards	2,1		
		Facing vertically downwards	2,0		
		Lying on the left side	2,0		
		Lying on the right side	2,0		

Conditioning : (T.C.) Temperature Conditioning

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.**

[redacted] 5.1.2e

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Article 7.16

Breathing Resistance : Exhalation

Condition	No. of Sample	The dummy head position	Exhalation Resistance: Flow Rate 160 L/min	Exhalation Resistance: Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	29	Facing directly	2,0	FFP1 ≤ 3 FFP2 ≤ 3 FFP3 ≤ 3	Passed
		Facing vertically upwards	2,0		
		Facing vertically downwards	2,0		
		Lying on the left side	2,0		
		Lying on the right side	2,0		
(A.R)	30	Facing directly	2,0		
		Facing vertically upwards	2,1		
		Facing vertically downwards	2,1		
		Lying on the left side	2,1		
		Lying on the right side	2,0		

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

Article 7.16

Breathing Resistance : Exhalation

Condition	No. of Sample	The dummy head position	Exhalation Resistance: Flow Rate 160 L/min	Exhalation Resistance: Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	31	Facing directly	2,2	FFP1 ≤ 3 FFP2 ≤ 3 FFP3 ≤ 3	Passed
		Facing vertically upwards	2,1		
		Facing vertically downwards	2,0		
		Lying on the left side	2,2		
		Lying on the right side	2,0		
(S.W)	1	Facing directly	2,2		
		Facing vertically upwards	2,2		
		Facing vertically downwards	2,2		
		Lying on the left side	2,2		
		Lying on the right side	2,0		

Conditioning : (A.R.) As Received, original
(S.W.) Simulated wearing treatment

Article 7.16

Breathing Resistance : Exhalation

Condition	No. of Sample	The dummy head position	Exhalation Resistance: Flow Rate 160 L/min	Exhalation Resistance: Requirements in accordance with EN 149:2001 + A1:2009	Result
(S.W.)	2	Facing directly	2,0	FFP1 ≤ 3 FFP2 ≤ 3 FFP3 ≤ 3	Passed
		Facing vertically upwards	2,2		
		Facing vertically downwards	2,2		
		Lying on the left side	2,2		
		Lying on the right side	2,0		
(S.W)	3	Facing directly	2,0		
		Facing vertically upwards	2,3		
		Facing vertically downwards	2,3		
		Lying on the left side	2,1		
		Lying on the right side	2,2		

Conditioning : (S.W.) Simulated wearing treatment

5.1.2e

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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.)	26	4,07		
(A.R.)	27	4,18		
(A.R.)	28	4,13	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 first and second protection class (FFP1, FFP2)
(S.W.)	4	3,95		
(S.W.)	5	3,88	FFP2 ≤ 6 %	
(S.W.)	6	3,86		
(M.S. T.C.)	10	4,05	FFP3 ≤ 1 %	
(M.S. T.C.)	11	4,17		
(M.S. T.C.)	12	3,98		

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.)	32	1,4	Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame	**Passed**
(A.R.)	33	1,3		
(T.C.)	21	1,2		Filtering half masks fulfill requirements of the standard
(T.C.)	22	1,1		

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.)	41	0,82	0,86	CO_2 content of the inhalation air shall not exceed an average of 1,0% by volume	**Passed**
(A.R.)	42	0,86			
(A.R.)	43	0,89			Filtering half masks fulfill requirements of the standard

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

Condition	Inhalation Resistance (mbar)					
	No. of Sample	Flow Rate 30 L/min	Requirements in accordance with EN 149:2001 + A1:2009	Flow Rate 95 L/min	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	29	0,4	FFP1 ≤ 0,6 FFP2 ≤ 0,7 FFP3 ≤ 1,0	1,3	FFP1 ≤ 2,1 FFP2 ≤ 2,4 FFP3 ≤ 3,0	Passed
(A.R.)	30	0,5		1,2		
(A.R.)	31	0,5		1,4		
(S.W.)	1	0,5		1,4		
(S.W.)	2	0,5		1,3		
(S.W.)	3	0,6		1,4		
(T.C.)	13	0,6		1,4		
(T.C.)	14	0,5		1,4		
(T.C.)	15	0,5		1,3		

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

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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 foreseenble 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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