

EU Declaration of Conformity

Regulation (EU) 2016/425

1. This EU Declaration of conformity refers to the following products:

Product Name	Model	Classification/Type	Reference Number
FFP2 Protective Particulate Respirators	ENM 712-0	CAT III	712001110 712005110

2. Manufacturer's name and address is as below:

Company Name	En Ecza Deposu İlaç Medikal Özel Sağlık Hizmetleri İnşaat Taahhüt Ticaret A.Ş.
Address	Saray Mahallesi Gıdacılar Caddesi 3670 Ada 2 Parsel Kahramankazan ANKARA/ TURKEY
AB Authorized Representative	ENMED B.V.
Address	Oudeweg 109A 2031 CC Haarlem Amsterdam NETHERLANDS

3. The Conformity assessment according to the essential requirements has been done by Easespal according to

EU Community Legislation

Personal Protective Equipment (PPE) Regulation (EU) 2016/425 Annex VII in connection with Annex V (Module C2) Certificate Number: 91-22-01-01 (White, Black, Normal Size, Small Size)

Harmonised standart:

EN 149:2001 + A1:2009 Respiratory Protective Devices -Filtering Half Masks to Protect Against Particles - Requiements, Testing, Marking (FFP2 NR)

Declaration Type:

MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ.

NB Number: 2841

This declaration is valid until:

This certificate is initially issued will be valid or 1 years from the issue date.

Place and Date of Issue:

Ankara / TURKEY

Date: 05.02.2022

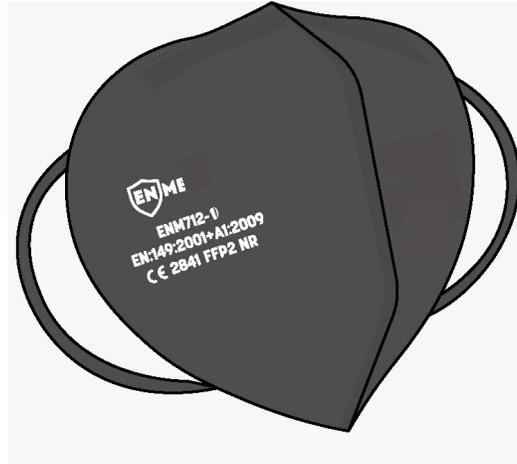
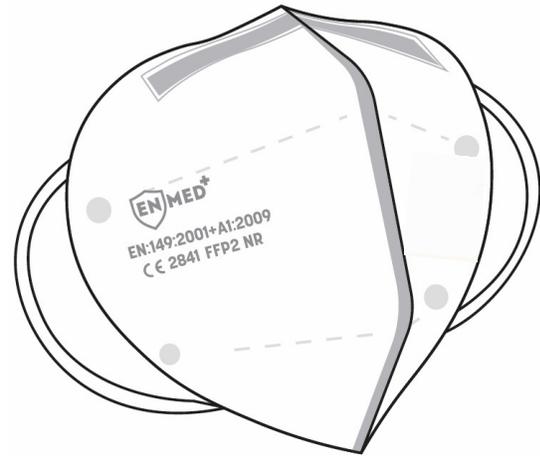
Company Sign:

EN ECZA DEPOSU İLAÇ MEDİKAL
ÖZEL SAĞLIK HİZM. A.Ş.

EN ECZA DEPOSU İLAÇ MEDİKAL ÖZEL SAĞLIK HİZMETLERİ
İNŞAAT TAAHHÜT TİCARET ANONİM ŞİRKETİ

Adres Atatürk Mah. 316 Sokak. İnşaat Apt. No: 8/B Merkez MERSİN
Adres No: 129432470 İstiklal V.D.: 3350707675
MERSİN NO: 0335030767500001 TİC. SİCİL NO: 51525
Tel: 0324 357 56 44 Fax: 0324 357 58 44

ENM 712-0 PROTECTIVE PARTICULATE RESPIRATORS WITHOUT VALVE (NORMAL SIZE & SMALL SIZE)



Fold design enables product to be easily stored when not in use. Diamond-shaped front allows the respirator to maintain its shape in hot humid environments. Single loop strap allows easy adjustment on the face and head.

ENM 712-0 is Particulate Respirators provide effective respiratory protection for use in industries where workers will be exposed to dust particles and/or non-volatile liquid particles.

Specification

Staps	:	Thermoplastic Elastomer	Nosefoam**	:	Polyurethane
Nose Clip	:	Steel/ Plastic	Size	:	Normal Size, Small Size
Color	:	White, Black			

ENM 712-0

PROTECTIVE PARTICULATE RESPIRATORS WITHOUT VALVE (NORMAL SIZE & SMALL SIZE)

Approvals

CE approved under PPE Directive (EU) 2016/425, Category III

Standards

These products meet the requirements of recently amended European Standard EN149:2001 + A1:2009, filtering facepiece respirators for use against particles. They should be used to protect the wearer from solid and non-volatile liquid particles only.

Products are classified by filtering efficiency and maximum total inward leakage performance (FFP1, FFP2 and FFP3), also by usability and clogging resistance.

Performance tests in this standard include filter penetration; extended exposure (loading) test; flammability; breathing resistance and total inward leakage. Reusable products are also subjected to cleaning, storage and mandatory clogging resistance tests

(clogging is optional for non reusable products). A full copy of

EN 149:2001+A1:2009 can be purchased from your national standards body. Designations:
R = Reusable

NR = Non reusable (single shift use only)

Storage and Disposal

- Store in dry, clean conditions in original packaging, away from direct sunlight, sources of high temperature, and solvent vapours
- Store within the temperature range -5°C to +25°C and with relative humidity below 80%
- Expected shelf life is three years from date of manufacture when stored as stated
- Replace garments if damaged, heavily contaminated or in accordance with local work practice or regulations
- Handle and dispose of contaminated garments with care and in accordance with applicable regulations.

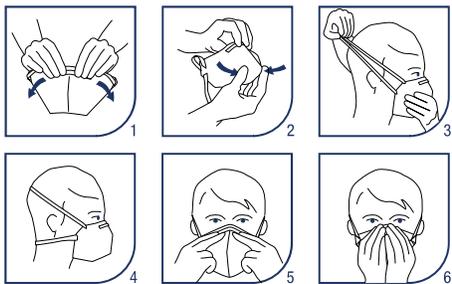
Fitting Instructions

1. With the respirator closed, shape the nosepiece as shown.
2. Open respirator, press in the central front panel and pinch the two points together as shown.
3. Cup respirator in one hand with open side towards face. Take both straps in other hand. Hold respirator under chin, with nosepiece up, and pull straps over head.
4. Locate the upper strap across the crown of the head and the lower strap below the ears. Straps must not be twisted.
5. Using both hands, mould noseclip to the shape of the lower part of the nose to ensure a close fit and good seal. Pinching the noseclip using only one hand may result in less effective respirator performance.
6. The seal of the respirator on the face should be fit-checked before entering the workplace.

Fit Check

1. Cover the front of the respirator with both hands being careful not to disturb the fit of the respirator.
2. a) UNVALVED respirator - EXHALE sharply;
3. If air leaks around the nose, re-adjust the noseclip to eliminate leakage. Repeat the above fit check.
4. If air leaks at the respirator edges, work the straps back along the sides of the head to eliminate leakage. Repeat the above fit check.

If you CANNOT achieve a proper fit DO NOT enter the hazardous area. See your supervisor.





ENM712-0

PROTECTIVE PARTICULATE RESPIRATORS WITHOUT VALVE (NORMAL SIZE & SMALL SIZE)

Warning and Limitation of Use

1. Always be sure that the complete product is: Suitable for the application; Fitted correctly; Worn during all periods of exposure; Replaced when necessary.
2. Proper selection, training, use and appropriate maintenance are essential in order for the product to help protect the wearer from certain airborne contaminants.
3. Failure to follow all instructions on the use of these respiratory protection products and/or failure to properly wear the complete product during all periods of exposure may adversely affect the wearer's health, lead to severe or life threatening illness or permanent disability.
4. For suitability and proper use follow local regulations, refer to all information supplied or contact a safety professional.
5. Before use, the wearer must be trained in use of the complete product in accordance with applicable Health and Safety standards.
6. These products do not contain components made from natural rubber latex.
7. These products do not protect against gases/vapours.
8. Do not use in atmospheres containing less than 19.5% oxygen. (Individual countries may apply their own limits on oxygen deficiency. Seek advice if in doubt).
9. Do not use for respiratory protection against atmospheric contaminants/ concentrations which are unknown or immediately dangerous to life and health (IDLH).
10. Do not use with beards or other facial hair that may inhibit contact between the face and the product thus preventing a good seal.
11. Leave the contaminated area immediately if:
 - a) Breathing becomes difficult.
 - b) Dizziness or other distress occurs.
12. Discard and replace the respirator if it becomes damaged, breathing resistance becomes excessive or at the end of the shift.
13. Never alter, modify or repair this device.

Applications

These respirators are suitable for use in concentrations of solid and non-volatile liquid particles up to the following limits:

Model	EN 149+A1 Classification	Exhalation Valve	Threshold Limit Value, TLV		
ENM - 712-0	FFP2 NR	Unvalved	12		
ENM - 712-1	FFP2 NR	Valved	12		

FILTERING MASK PERFORMANCES				
Classification	Penetration of Filter Material by an Aerosol (the following filter penetration parameters shall not be exceeded) Test aerosol made of Sodium chloride - Paraffin oil 95l/min % Max.	Maximum Permitted Breathing Resistance applicable to both valved and valvless filtering half-masks (mbar)		
		Inhalation flow		Exhalation flow
		30 l/min	95 l/min	160 l/min
FFP2	6 %	0,7	2,4	3,0



ENM712-0 PROTECTIVE PARTICULATE RESPIRATORS WITHOUT VALVE (NORMAL SIZE & SMALL SIZE)

SELECTION GUIDE

		FFP1	FFP2	FFP3	Organic Vapour	Acid Gas	Welding
Painting, Varnishing, Spraying, Coating, Mixing	Solvent-Based - brush / roller applied			•	•		
	Solvent-Based - spray applied						
	Water-Based - brush / roller / spray applied			•	•		
	Wood Preservatives			•	•		
	Powder Coating			•			
Sanding, Stripping, Grinding, Cutting, Drilling	Rust, most Metals, Filler, Concrete, Stone	•					
	Cement, Wood, Steel,		•				
	Paints, Varnish, Anti-rust coating		•				
	Stainless Steel, Anti-fouling varnish			•			
	Resins, Reinforced plastics (carbon / glass fibre)		•	•			
Construction / Maintenance	Scabbling, Shot-creting (concrete dust)	•	•	•			
	Plastering, Rendering, Cement mixing	•	•	•			
	Demolition	•	•				•
	Groundwork, Earth moving, Piling, Underpinning		•	•			
	Spray foam, Loft Insulation		•	•			
Metal working / Foundries	Welding, Soldering		•	•			•
	Electro-plating		•	•		•	
	Finishing, Slotting, Drilling, Riveting, Machining		•	•			
	Oxyacetylene cutting		•	•			
	Molten metal handling, Smelting		•	•		•	
Cleaning / Waste Removal	Disinfection, Cleaning		•	•	•	•	
	Waste removal		•	•	•		
	Asbestos handling			•			
	Asbestos removal						
Allergens / Biohazards	Pollen, Animal dander	•					
	Mould / Fungus, Bacteria**, Viruses		•	•			
	**Tuberculosis			•			
	Diesel exhaust / Smoke		•				
Agriculture / Forestry	Handling infected animals, Culling		•	•	•		
	Feeding livestock, Cleaning sheds / harvesters	•	•	•			
	Straw chopping, Composting, Harvesting		•	•			
	Pesticides, Insecticides (crop spraying)		•	•	•		
Mining / Quarrying	Tunnelling, Drilling, Grinding, Excavation		•	•			
	Pumping, Dredging, Washing		•	•			
	Cutting, Sawing		•	•			
	Changing Filters		•	•			
Other Industrial Applications	Inks, Dyes, Solvents, Chemicals		•	•	•		
	Powdered Additives / Chemicals		•	•	•		
	Pharmaceuticals		•	•	•		
	Rubber / Plastics processing		•	•	•		
	Oil and Gas Extraction / Processing		•	•	•	•	•
	Pottery, Ceramics			•			
	Wood / Paper Mills		•	•			

Specification Sheet | Respirators

**CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED
PRODUCT CHECKS AT RANDOM INTERVALS (MODULE C2)**

**MODÜL C2 - ÜRETİMİN DÂHİLÎ KONTROLÜ VE ÜRÜNÜN RASTGELE
ARALIKLARLA DENETİMLİ MUAYENESİNE DAYALI TİPE UYGUNLUK**

Belge No / Certificate No	: 91-22-01-01-R01
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi / Certification Date / Certificate Validity Date	: 05.02.2022-31.01.2023
Belge Geçerlilik Tarihi / Document Validity Period	: 1 yıl / 1 year
Firma Unvanı ve Adresi / Company Name and Address	: EN ECZA DEPOSU İLAÇ MEDİKAL ÖZEL SAĞLIK HİZMETLERİ İNŞAAT TAAHHÜT TİCARET A.Ş. Saray Mahallesi, Gıdacılar Caddesi, No:18, Kahramankazan/ANKARA
Ürün Adı /Modeller / Product Name / Models	: ENM-712-0
Direktifi / Directive	: 2016/425 REGULATION
Modülü/Kategori / Module / Category	: C2 MODÜLÜ/ KATEGORİ III MODULE C2 / CATEGORY III
Teknik Değerlendirme Rapor No/ Technical Evaluation Report No	: MNA 91-22-01-R01
Ürün Tipi / Product Type:	
- EN 149:2001+ A1:2009 Solunumla ilgili koruyucu cihazlar- Parçacıklara karşı koruma amaçlı filtrelili yarım maskeler/ Respiratory protective devices - Filtering half masks to protect against particles	

Ürünün Malzeme Bilgisi / Product Material Information: ENM-712-0 model ürünleri kumaş, elastik kayış, burun klipsi, filtre katmanı kullanılarak imal edilmiştir. / ENM-712-0 products are manufactured using fabric, elastic strap, nose clip, filter layer.

Revizyon nedeni / Reason for revision: Farklı renk ve beden eklenmiştir. / Different size and color have been added.

Volkan AKIN
05.02.2022

Karar Verici / Approver



Okan AKEL
05.02.2022

Şirket Müdürü / General manager



AB Tip İnceleme Sertifikası EU Type-Examination Certificate

Belge No / Certificate No : 91-22-01-R01
**Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date** : 05.02.2022-12.01.2027
Belge Geçerlilik Tarihi / Document Validity Period : 5 yıl / 5 years
**Firma Unvanı ve Adresi /
Company Name and Address** : EN ECZA DEPOSU İLAÇ MEDİKAL ÖZEL
SAĞLIK HİZMETLERİ İNŞAAT TAAHHÜT
TİCARET A.Ş.
Saray Mahallesi, Gıdacılar Caddesi, No:18,
Kahramankazan/ANKARA
Ürün Adı /Modeller / Product Name / Models : ENM-712-0
Direktifi / Directive : 2016/425 REGULATION
Modülü/Kategori / Module / Category : B MODÜLÜ/ KATEGORİ III
MODULE B / CATEGORY III
**Teknik Değerlendirme Rapor No/
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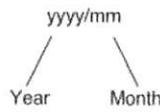
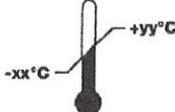
ATTACHMENTS (91-22-01-R01)

To certify the PPE product at Category III level, C2 or D module is accompanied by applying one of the conformity assessment methods along with the EU Type Examination (Module B).

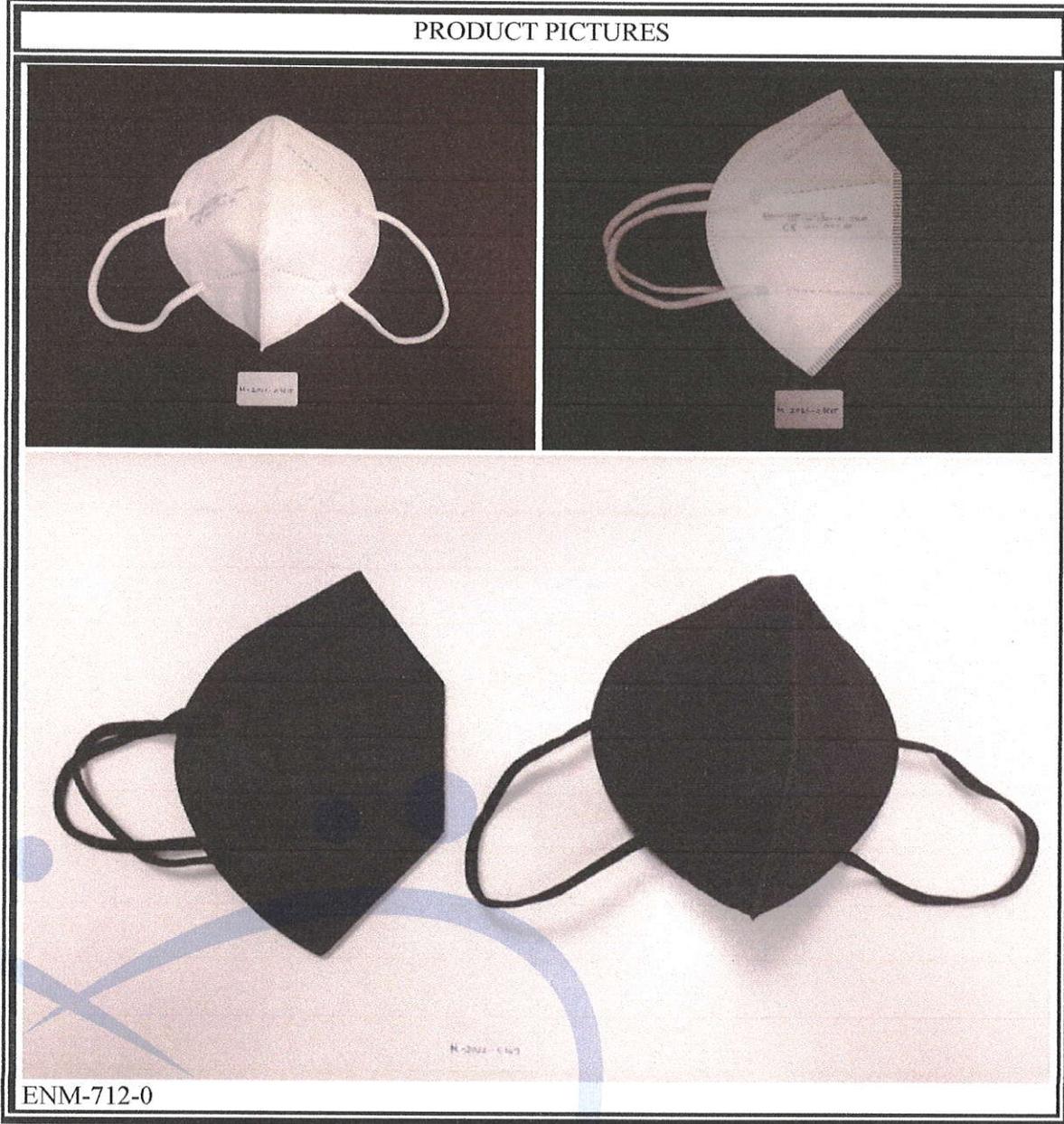
Model : ENM-712-0

PPE SPECIFICATION	PERFORMANCE LEVELS
Classification	FFP2
Reusable / Single Shift Use	NR

PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model:

MARKING					
MANUFACTURER: EN ECZA DEPOSU İLAÇ MEDİKAL ÖZEL SAĞLIK HİZMETLERİ İNŞAAT TAAHHÜT TİCARET A.Ş.					
PPE TYPE:					
- EN 149:2001+ A1:2009 Respiratory protective devices - Filtering half masks to protect against particles					
MODEL: ENM-712-0					
PRODUCT SIZE: Standard and small					
PICTOGRAM AND PERFORMANCE LEVELS:					
EN 149:2001+ A1:2009 FFP2 NR					
					
NB 2841		Or Condition of Storage			

MNA LABORATORIES SAN. TIC. LTD. ŞTİ declares that the above-mentioned product meets the requirements of the directive according to the EU Directive 2016/425, the safety of the product is covered by the conditions and use specified in this certificate and in the technical file.

ATTACHMENTS (91-22-01-R01)**DOCUMENTS IN THE TECHNICAL FILE**

- Basic Health Safety Requirements
- Risk Assessment
- Test Reports
- Technical Report

Report No : 91-22-01-R01

Report Date : 05.02.2022

Application No : 91-22-01

1. COMPANY INFORMATION:

EN ECZA DEPOSU İLAÇ MEDİKAL ÖZEL SAĞLIK HİZMETLERİ İNŞAAT TAAHHÜT TİCARET A.Ş.
Saray Mahallesi, Gıdaçılar Caddesi, No:18, Kahramankazan/ANKARA

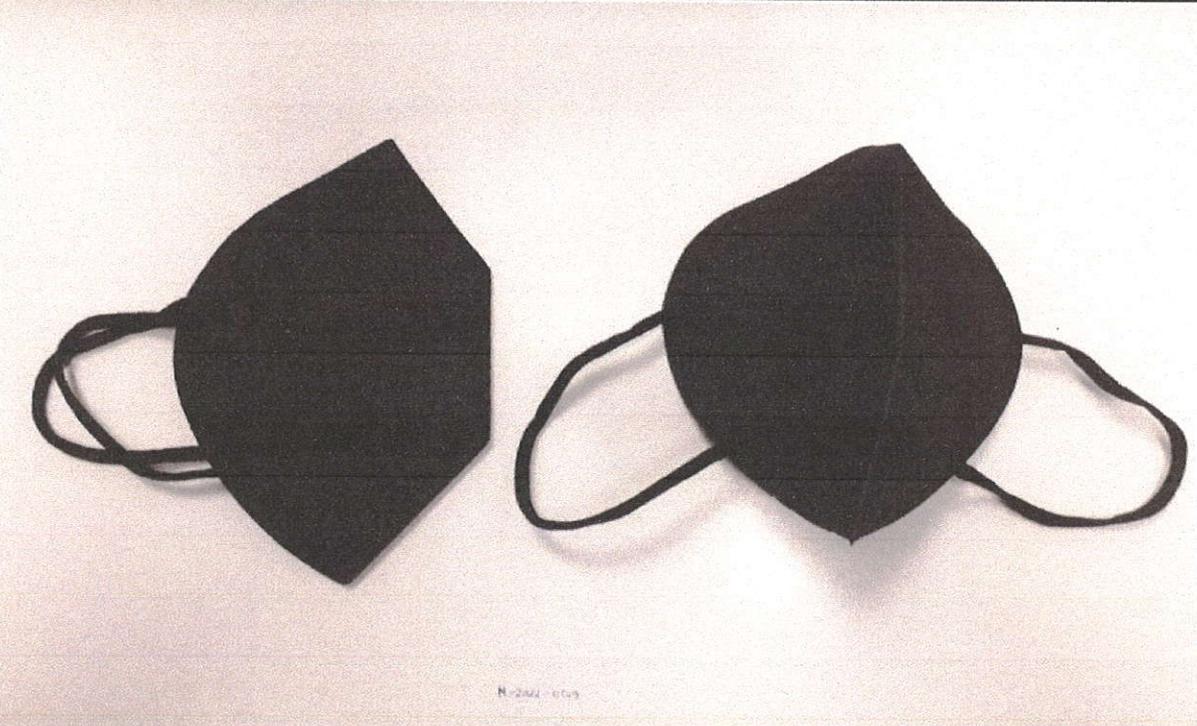
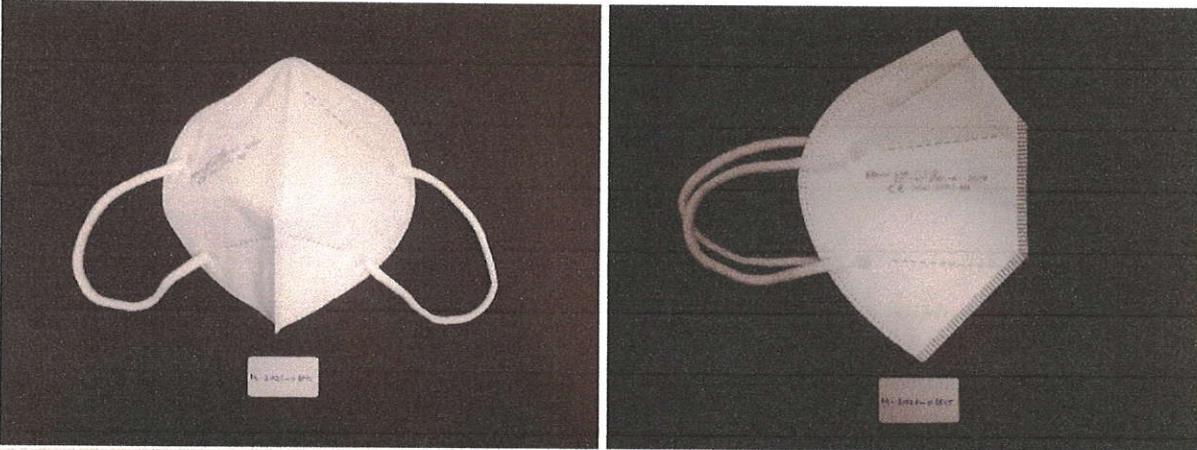
2. PPE INFORMATION:

Disposable and non-sterile half mask made of particulate protection filter material.

3. PPE TYPE IDENTIFICATION

EN 149:2001+A1:2009 Respiratory protective devices – Filtering half masks to protect against particles - Requirements, testing, marking

4. PPE PICTURES



ENM-712-0

5. PPE DIMENSIONS:

ENM-712-0 model has been found to be produced using standard and small sizes.

6. PPE PRODUCT MATERIAL INFORMATION:

The product is made of elastic strap, nonwoven fabric on the outer and inner layers and filter material on the middle layer.

7. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

- A visual inspection was made according to EN 149:2001 +A1:2009 for ergonomics.
- Protection levels and degrees are defined by the manufacturer.
- Suitable construction materials were determined by visual inspection according to EN 149:2001 +A1:2009.

8. ANALYSIS AND EVALUATIONS:

EN 149:2001 +A1:2009

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.3 Visual inspection	Shall also the marking and the information supplied by the manufacturer				Appropriate	-	PASS
Banned Azo Dyes	< 30 mg/kg				< 5 mg/kg	-	PASS
Part 7.4 Packaging	Particle filtering half mask shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.				Appropriate	-	PASS
Part 7.5 Material	When conditioned in accordance 8.3.1 & 8.3.2 the particle filter half mask shall not collapse.				Appropriate	-	PASS
Part 7.6 Cleaning and disinfecting	After cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.				Not applicable	-	Not applicable
Part 7.7 Practical performance	No negative comments should be made by the test subject regarding any of the criteria evaluated.				Appropriate	-	PASS
Part 7.8 Finish of parts	Parts of the device likely to come into contact with the wearer shall have no sharp edge or burrs.				Appropriate	-	PASS

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.9.1 Total inward leakage	At least 46 out of the 50 individual exercise result	<25	<11	<5	See the table below	FFP2	PASS

	At least 8 out of the 10 individual wearer arithmetic means	<22	<8	<2	See the table below	FFP2	PASS
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Total Inward Leakage (%)						
	Exercise 1	Exercise 2	Exercise 3	Exercise 4	Exercise 5	Average
Subject 1 (As received)	3,9	4,2	4,5	3,8	3,5	4,0
Subject 2 (As received)	6,8	5,9	7,0	5,9	5,7	6,3
Subject 3 (As received)	4,5	4,2	5,2	5,0	4,4	4,7
Subject 4 (As received)	4,2	4,0	3,5	4,5	4,6	4,2
Subject 5 (As received)	4,6	5,0	5,2	5,4	4,7	5,0
Subject 6 (After temperature conditioning)	3,9	3,8	3,4	5,0	5,1	4,2
Subject 7 (After temperature conditioning)	5,5	5,1	6,4	4,9	6,2	5,6
Subject 8 (After temperature conditioning)	6,8	7,2	6,6	6,4	4,9	6,4
Subject 9 (After temperature conditioning)	3,5	3,6	2,9	2,9	2,7	3,1
Subject 10 (After temperature conditioning)	4,5	5,3	5,2	4,1	4,5	4,7

Subject facial dimensions

Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
1	133	132	132	65
2	125	144	116	67
3	126	135	124	75
4	123	133	134	74
5	117	135	122	73
6	122	142	133	66
7	113	132	114	75
8	135	123	123	65
9	122	135	133	74
10	135	142	125	83

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.9.2 Penetration of filter material	Sodium chloride, 95 L/min % max	% 20	% 6	% 1	See the table below	FFP2	PASS
	Paraffin oil, 95 L/min % max	% 20	% 6	% 1	See the table below	FFP2	PASS

Penetration of filter material	Sodium Chloride (%)	Paraffin Oil (%)
As received	1,2	1,6
As received	1,4	1,5
As received	1,3	1,5

After the simulated wearing treatment	1,2	1,7
After the simulated wearing treatment	1,2	1,8
After the simulated wearing treatment	1,5	1,5
Mechanical strength and temperature conditioning (120 mg)	1,8	2,2
Mechanical strength and temperature conditioning (120 mg)	1,9	2,1
Mechanical strength and temperature conditioning (120 mg)	1,9	2,2

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.10 Compatibility with skin	Materials shall not be known to be likely to cause irritation or any other adverse effect to health				Appropriate	-	PASS
Part 7.11 Flammibility	Mask shall not burn or not to continue to burn for more than 5 s				Flame not seen	-	PASS
Part 7.12 Carbondioxide content of the inhalation air	Shall not exceed an average of % 1				0,80 0,78 0,85	-	PASS
Part 7.13 Head harness	It can be donned and removed easily				Appropriate	-	PASS
Part 7.14 Field of vision	The field of vision shall acceptable in practical performance test.				Appropriate	-	PASS
Part 7.15 Exhalation valve(s)	It shall withstand axially a tensile force of 10 N apply for 10 s. If fitted, shall continue to operate correctly after a continuous exhalation flow of 300 L/min over a period of 30 s.				Not applicable	-	Not applicable

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.16 Breathing Resistance	Inhalation 30L/min	0,6 mbar	0,7 mbar	1,0 mbar	See the table below	FFP2	PASS
	Inhalation 95L/min	2,1 mbar	2,4 mbar	3,0 mbar	See the table below	FFP2	PASS
	Exhalation 160L/min	3,0 mbar	3,0 mbar	3,0 mbar	See the table below	FFP2	PASS

Breathing Resistance (mbar)	Inhalation 30L/min	Inhalation 95L/min
As received	0,5	1,6
As received	0,5	1,6
As received	0,4	1,5
After temperature conditioning	0,5	1,6
After temperature conditioning	0,5	1,5
After temperature conditioning	0,4	1,5
After the simulated wearing treatment	0,5	1,5
After the simulated wearing treatment	0,5	1,6
After the simulated wearing treatment	0,4	1,5

Breathing Resistance 160L/min (mbar)	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side
As received	2,8	2,7	2,8	2,8	2,7
As received	2,7	2,8	2,7	2,7	2,8
As received	2,7	2,7	2,7	2,7	2,7
After temperature conditioning	2,7	2,7	2,7	2,7	2,8
After temperature conditioning	2,8	2,7	2,8	2,7	2,7
After temperature conditioning	2,8	2,7	2,8	2,7	2,8
After the simulated wearing treatment	2,8	2,8	2,7	2,7	2,8
After the simulated wearing treatment	2,7	2,7	2,7	2,7	2,8
After the simulated wearing treatment	2,7	2,8	2,7	2,8	2,7

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.17 Clogging	After clogging the inhalation resistances shall not exceed. (valved)	4 mbar	5 mbar	7 mbar	Not applicable	-	Not applicable
	The exhalation resistance shall not exceed 3 mbar at 160 L/ min continuous flow. (valved)				Not applicable	-	Not applicable
	After clogging the inhalation and exhalation resistances shall not exceed. (valveless)	3 mbar	4 mbar	5 mbar	Not applicable	-	Not applicable
Part 7.18 Demountable part	All demountable parts (if fitted) shall be readily connected and secured were possible by hand.				Not applicable	-	Not applicable

9. DECISION PROPOSAL

Analysis and examinations ENM-712-0 model coded personal protective equipment; Respiratory Protective Devices EN 149:2001 +A1:2009- Filtered Half Masks for Protection Against Particles - Properties, Experiments and Marking standards are evaluated. It is recommended to be certified at the performance levels specified as a result of technical evaluations.

10. ATTACHMENTS

- Basic Health Safety Requirements
- Risk Assessment
- Test Report (M-2021-01815, M-2022-0149)
- User Instruction

CONTROLLER : VOLKAN AKIN

SIGNATURE :

DATE : 05.02.2022

