

**NB 2163** 

# **EU TYPE EXAMINATION CERTIFICATE**

Certificate No: 2163-PPE-1706

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

## En Ecza Deposu İlaç Medikal Özel Sağlık Hizmetleri İnşaat Taahhüt Ticaret A.Ş.

Atatürk Mah. 31043 Sok. Kubat Apt. No :8/B Mezitli / Mersin TURKEY Manufacturing Site:

Karaduvar Mah. Serbest Bölge 7. Cad. No :21 33020 Akdeniz / Mersin TURKEY 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**

Single use particle filtering half mask for protection against solid and liquid aerosols, foldable, with high filtration and low breathing resistance, 5 layered, without valve, with elastic ear strap and adjustable nose bar.

Brand Name: ENMED Model: ENM-712 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 24/11/2020 and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

**CE** 2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director



Verify the validity with the QR code



## TECHNICAL EVALUATION REPORT

REPORT DATE / NO: 24.11.2020 / 2163-KKD-1706

Manufacturer: En Ecza Deposu İlaç Medikal Özel Sağlık Hizmetleri İnşaat Taahhüt Ticaret A.Ş. Headoffice Address: Atatürk Mah. 31043 Sok. Kubat Apt. No :8/B Mezitli / Mersin TURKEY Factory Address: Karaduvar Mah. Serbest Bölge 7. Cad. No :21 33020 Akdeniz / Mersin TURKEY

#### Introduction

This report is for the, given above, manufacturer prepared according to the test results obtained from Universal Certification And Surveillance Services Trade Co., dated 16.11.2020 with report number 11-2020-T0510 based on EN 149: 2001 + A1: 2009 standard and the technical file dated 02 November 2020 Revision 00 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 Personel Protective Equipment Regulation and found to be appropriate.

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

**Product Description:** Single use particle filtering half mask for protection against solid and liquid aerosols, foldable, with high filtration and low breathing resistance, 5 layered, without valve, with elastic ear strap and adjustable nose bar.

#### Component and Materials:

Component	Material	Grade	
1st Layer	Non-Woven	50g/m²	7/13
2nd Layer	Meltblown	25g/m²	
3th Layer	Air Filter Cotton	50g/m²	
4th Layer	Meltblown	25g/m²	
5th Layer	Non-Woven	20g/m²	

Classification: FFP2 NR

Brandname: ENMED Model: ENM-712



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### 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 prossible level.

#### 1.1.2. Levels and classes of protection

#### 1.1.2.1. Highest level of protection possible

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

#### 1.1.2.2. Classes of protection appropriate to different levels of risk

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

#### 1.2. Innocuousness of PPE

#### 1.2.1. Absence of risks and other inherent nuisance factors

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

#### 1.2.1.1. Suitable constituent materials

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

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

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

#### 1.2.1.3. Maximum permessible user impediment

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

#### 1.3 Comfort and effectiveness

#### 1.3.1. Adaptation of PPE to user morphology

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

#### 1.3.2. Lightness and design strength

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

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

#### 1.4. Information supplied by the manufacturer

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

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

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



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## 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

#### 3.10.1. 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.

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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

	C	onforming to EN	149:2001 + A1:2009 S	tandard Red	quirements				
Article		cle Filtering Half Masl				The second secon			
Article 5			e test results and technical fil		the manufacturer is classified	l as;			
		Filtering Efficiency and Maximum Total Inward Leakage: Classified as FFP2  Mask is classified for single shift use, NR							
Article	mechanical damage	Packing: Particle filtering half masks are packaged to protect them from contamination before use and with cardboard boxes to prevent							
.4		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.							
		Material: Materials used in particle filtering half masks, according to the simulated wearing treatment and temperature conditioning results; It is							
	understood it withsta	ands handling and wear	r over the period for which th	e particle filter	ing half mask is designed to	be used, it suffered mechan			
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.5	nuisance for the wea	irer. The manufacturer	declares that the materials	ised in manufa	cturing of the mask does no	t have an adverse affect to			
	health and safety of								
			ot collapse when subject to	simulated wear	ring and temarature condition	oning. No nuisance situation			
			ests by human subjects.						
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.6	manufacturer.								
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	3.Secur	ity of fastenings	2	0	subject				
		of vision	2	0	No imperfe	ctions			
	Conditioning: (A.R.	.) As Received, origina	ıl						
Article	Finish of Parts: Par	ticle filtering half ma	sks, which are likely to com	e into contact	with the user, do not have s	harp edges and do not cor			
.8	burrs.								
	<b></b>	Total Inward Leakage:							
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(T.C.) Temperature Conditioning (A.R.) As Received, original (S.W.) Simulated wearing treatment



			F	Penetration of filte	r material: Parafi	in Oil Testing			
	Co	ndition	No. of Sample	Paraffin Oil 95 L/min m		quirements in accordance in EN 149:2001 + A1:2009		Result	
		(A.R.)	39	0,52	10.00 mm (10.00 mm)				
	4	(A.R.)	40	0,46					
		(A.R.)	41	0,32		FFP1 ≤ 20 %	Filtering 1	nalf masks fulfill the	
Article		(S.W.)	4	0,44		FFF1 ≤ 20 %	requirem	ents of the standard	
7.9.2		(S.W.)	5	0,49		FFP2 ≤ 6 %		49:2001 + A1:2009	
		(S.W.)	6	0,45		1112 20 70		1.9.2 in range of the	
	(M	.S. T.C.)	13	0,56		FFP3 ≤ 1 %	FFP1,	FFP2 and FFP3	
	(M.	S. T.C.)	14	0,61		X		classes.	
	(M	.S. T.C.)	15	0,53					
*	()	Γ.C.) Temperat A.R.) As Recei	ture Conditioning						
Article 7.10		th skin: In Pra	actical Performan		ihood of mask m	aterials in contact with the	skin causi	ng irritation or other	
	Flammability:								
	Condition	No. of Sample		ual inspection	Requirer	nents in accordance with E 149:2001 + A1:2009	N	Result	
Article	(A.R.) 45		Bı	ırn for 0.0s		Filtering half mask		Passed	
7.11		(A.R.) 46				shall not burn or not			
7.11	(T.C.)	(T.C.) 21		ırn for 0.0s		continue to burn for	Filtering half masks fulfill		
	(T.C.)	22	Bı	Burn for 0.1s		more than 5 s after		equirements of the	
	Conditioning: (A.R.) As Received, original						standard		
			ure Conditioning						
	Carbon dioxide c								
Article	Condition No. of Sample		CO <sub>2</sub> content of t	VCCC 6FF666CGD F73866CGD FCCC FF6386GGB+1c Tale=F055	An average CO <sub>2</sub> content of the inhalation air Requirements in according to the inhalation air				
7.12	(A.R.)	26	0,53		un		in (1 control for continue) (in	Passed	
	(A.R.)	27	0,52			CO2 content of the inhal	lation air	1 asseu	
	(A.R.)	28		0,54		shall not exceed an ave 1,0% by volume	an average of Filtering half i		
	Conditioning: (A.								
Article 7.13	Head harness: In results of these tes	Practical Perfets indicates that	ormance and TIL at the ear loops / h	test reports no ad ead harness are ca	verse effects have apable of holding	e been reported for donning the mask firmly enough.	g and remo	ove of the mask also th	
Article 7.14	Field of vision: In	Practical Perf	ormance report, n	o adverse effects	were reported for	the field of vision availabi	lity when	the mask is weared.	
Article 7.15	Exhalation Valve No exhalation valv	, ,	nples.						
	Breathing Resista	nce: Inhalatio	on						
Article 7.16	The overall evalua treatment condition L/min and exhalati	ned complies v	with the limits giv	9 different samp en in the standar	les 3 as received d for FFP2,FFP3	, 3 with temparature cond classes. This is valid for in	itioning an	nd 3 simulated wearing sesults for 30 L/min, 9	
	Passed.								





Article 7.17	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 7.18	Demountable Parts: There are no demountable parts on the product.
Article 8	Testing: 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.
	Marking – Packaging: 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 1 of the technical file.
Article 9	The technical documentation for mask design (drawing) also evaluated for marking requirements, drawing ENM-712. The mask marking indicates that the mask will carry information about the brandname (ENMED) 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. The tested samples by the laboratory do not carry necessary marking information as stated in the technical documentation, the manufacturer shall also follow marking instructions for serial production. Model ENM-712 drawing exists in the technical file of the manufacturer, Section 10 of technical file.
Article	Information to be supplied by the manufacturer: 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 2. The manufacturer shall include this documented user information text in every smallest commertially available package.





## UNIVERSAL CERTIFICATION and SURVEILLANCE SERVICES TRADE CO.

Necip Fazil Bulvari Keyap Sitesi E2 Blok No:44/84 Yukari Dudullu Umraniye, Istanbul / TURKEY

## **TEST REPORT**

**Report Date:** 16.11.2020 **Report Number:** 11-2020-T0510

#### **CLIENT and SAMPLE INFORMATION**

TEST OWNER	En Ecza Deposu İlaç Medikal Özel Sağlık Hizmetleri İnşaat Taahhüt Ticaret A.Ş.					
ADDRESS	Atatürk Mah. 31043 Sok. k	Atatürk Mah. 31043 Sok. Kubat Apt. No :8/B Mezitli / Mersin				
MANUFACTURER ADDRESS	Karaduvar Mah. Serbest Bo	ölge 7. Cad. No :21 33020	Akdeniz / Mersin TURKEY			
SAMPLE DESCRIPTION	Folding type protective ma	sk				
BRAND NAME - MODEL	ENMED / ENM-712					
TESTING STANDARD	EN 149+A1:2009					
CASE NUMBER	CE-PPE-3644					
SAMPLE RECEIVE DATE	27.10.2020 TE	ESTING START DATE	27.10.2020			
DISINFECTION INSTRUCTION  If applicable	Not given, single use only					
NUMBER OF SAMPLES	50 SAMPLE I	Ds: 1 – 46				
AS RECEIVED SAMPLE NO	26-46					
	Simulated wearing treatment	1-2-3-4-5-6-7-8-9 (As Received)				
CONDITIONING SAMPLE NO	Temperature conditioning	10-11-12-13-14-15 (Sample after test of Mechanical Strength)				
		16-17-18-19-20-21-22-23-24-25 (As Received)				
	Mechanical strength 10-11-12-13-14-15 (As Received)					

The results given in this test report belongs to the samples tested. The report content cannot be recreated partially without the written consent of UNIVERSAL CERTIFICATION.

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Suat KAÇMAZ
Director



## 1. REPORT SUMMARY

TEST STANDARD	TEST NAME	RESULT	EVALUATION	
EN 149:2001 +				
A1:2009 clause 8.5	Total Inward Leakage Testing	Pass	FFP2	
EN 13274-1:2001		1 455	1112	
EN 149:2001 +		1.7 61 . 4		
A1:2009 clause 8.11	Penetration of Filter Material	Pass	FFP3	
EN 13274-7:2019		1 455	1113	
EN 149:2001 +				
A1:2009 clause 8.6	Flammability Testing	Pass	See results	
EN 13274-4:2001		T acos	See results	
EN 149:2001 +				
A1:2009 clause 8.7	Carbon Dioxide Content of The Inhalation	Pass	See results	
EN 13274-6:2001	Air Testing		See resures	
EN 149:2001 +	Breathing Inhalation Resistance-30 l/min	Pass	Can wante	
A1:2009 clause 8.9	Breathing initiation resistance-50 l/illin	rass	See results	
EN 13274-3:2001	Breathing Inhalation Resistance-95 l/min	Pass	See results	
EN 149:2001 +	*			
A1:2009 clause 8.9	Exhalation Resistance, flow rate 160 l/min	Pass	See results	
EN 13274-3:2001		2 8600	See resuits	





## 2. TEST RESULTS and EVALUATION

## 7.4 PACKAGING (EN 149:2001 + A1:2009 clause 8.2)

Test Method: Clause 8.2-Visual inspection

REQUIREMENT	RESULTS	COMMENT
Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	Pass	The masks were packaged in sealed plastic bags, in larger plastic bags inside a large cardboard box that gave some protection against mechanical damage or contamination before use

Lab A

## 7.5 MATERIAL (EN 149:2001 + A1:2009 clause 8.2, 8.3.1, 8.3.2)

Test Method: Clause 8.2-Visual inspection

Clause 8.3.1-Simulated wearing treatment

A breathing machine is adjusted to 25 cycles/min and 2,0 l/stroke. The particle filtering half mask was mounted on a Sheffield dummy head.

For testing, a saturator is incorporated in the exhalation line between the breathing machine and the dummy head, the saturator being set at a temperature in excess of 37 °C to allow for the cooling of the air before it reaches the mouth of the dummy head.

The air has been saturated at  $(37 \pm 2)$  °C at the mouth of the dummy head

Clause 8.3.2-Temperature conditioning

The ambient temperature for testing has been between 16 °C and 32 °C and the temperature limits has been subject to an accuracy of  $\pm 1$  °C.

- a) for 24 h to a dry atmosphere of  $(70 \pm 3)$  °C;
- b) for 24 h to a temperature of  $(-30 \pm 3)$  °C; and allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing. The conditioning has been carried out in a manner which ensures that no thermal shock occurs.

REQUIREMENT	RESULTS	COMMENT
Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.	Pass	The materials used were able to withstand handling and wear during the limited laboratory testing carried out.
Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Pass	It was not constitute a hazard or nuisance for the wearer.
After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.	Pass	None of the specimens conditioned suffered mechanical failure.
When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Pass	None of the specimens had not collapse after conditioning.

Lab B





## 7.6 CLEANING AND DISINFECTING (EN 149:2001 + A1:2009 clause 8.4, 8.5, 8.11)

Test Method: Described in Clause 8.4, 8.5 and 8.11

REQUIREMENT	RESULTS	COMMENT
If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.  With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.	N/A	This article is not applicable for tested protective mask which is single use disposable mask.

#### 7.7 PRACTICAL PERFORMANCE (EN 149:2001 + A1:2009 clause 8.4)

Test Method: Described in Clause 8.4

REQUIREMENT	RESULTS	COMMENT
The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that can not be determined by the tests described elsewhere in this standard.	No imperfections	Detail refer to Annex I
Two as received mask samples are used by two subject for the walking (10 mins walking with a speed of 6km/h) and work simulation (bended walking, crawling and basket filling exercises) tests.		

#### **Annex I-Test Result:**

Number of sample: 29 (A.R), 30 (A.R)

Assessed elements	Positive Assessment	Negative Assessment	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
The face piece fitting Head harness comfort Security of fastenings Field of vision	2 2 2 2 2	0 0 0 0	Filtering half masks should not have imperfections related to wearer's acceptance	Filtering half masks fulfil requirements of the standard EN 149:2001 + A1:2009 given in 7.7 No imperfections

The subjects (MEG and MA) were able to complete the exercises and did not report any nuisance or problem with the mask. Lab B

## 7.8 FINISH OF PARTS (EN 149:2001 + A1:2009 clause 8.2)

Test Method: Described in Clause 8.2

REQUIREMENT	RESULTS	COMMENT
Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	Pass	None of the specimens used in laboratory testing showed evidence of sharp edges or burrs while visual inspection
		and performance tests.

Lab A

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## 7.9.1 TOTAL INWARD LEAKAGE (EN 149:2001 + A1:2009 clause 8.5)

Test Method: Described in Clause 8.5

REQUIREMENT	RESULTS	COMMENT
The total inward leakage consists of three components: face seal leakage, exhalation value leakage (if exhalation value fitted) and filter penetration. For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual results shall be not greater than: 25 % for FFP1, 11 % for FFP2, 5 % for FFP3 and in addition at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall not be greater than: 22 % for FFP1, 8 % for FFP2, 2 % for FFP3	Pass	Classified as FFP2  Detail refer to Annex II

#### **Annex II-Test Result:**

The test results obtained are given in the tables as follows

Test Subject	No of sample	Cond.	1. Walk (%)	Head side/ side (%)	Head up/down (%)	Talk (%)	2. Walk (%)	Average (%)
1	31	A.R.	7,02	7,11	7,32	7,21	7,51	7,23
2	32	A.R.	7,12	7,36	7,48	7,63	7,72	7,46
3	33	A.R.	7,06	6,99	7,31	7,46	7,87	7,33
4	34	A.R.	7,16	7,25	7,46	7,68	7,77	7,46
5	35	A.R.	7,27	7,38	7,52	7,65	7,79	7,52
6	16	T.C.	6,79	7,07	7,39	7,47	7,93	7,33
. 7	17	T.C.	7,16	7,24	7,21	7,56	7,61	7,35
8	18	T.C.	7,33	7,44	7,70	7,86	8,03	7,67
9	19	T.C.	7,39	7,58	7,73	7,81	7,96	7,69
10	20	T.C.	6,98	7,16	7,55	7,63	7,84	7,43
All 50 indiv	vidual exercise vidual wearer	e results were arithmetic me	not greater than	n 11 % reater than 8 %				Pass (FFP2)

Test Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
1	117	155	130	60
2	113	148	128	62
3	112	160	134	59
4	115	148	125	61
5	120	158	132	57
6	118	150	134	59
7	115	152	130	57
8	117	155	134	59
9	114	149	128	57
10	110	150	131	55

For Information Only

Lab E





## 7.9.2 PENETRATION OF FILTER MATERIAL (EN 149:2001 + A1:2009 clause 8.11)

Test Method: Described in Clause 8.11

REQUIREMENT		RESULTS	COMMENT	
FFP1 FFP2 FFP3	Max penetration NaCl test 95 l/min %max 20 6	Paraffin oil test 95 l/min %max 20 6 1	Pass	Detail refer to Annex IIIA and IIIB

#### **Annex IIIA-Test Result:**

The test results obtained are given in the tables as follows;

Condition	Penetration of Sodium Chloride in accordance with EN 13274- 7:2019 [%] Flow rate 95 l/min	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
As received	0,09		Passed
		FFP1 ≤ 20 %	Filtering half masks fulfil the
Simulated wearing treatment	0,32	FFP2 ≤ 6 %	requirements of the standard EN 149:2001+A1:2009 given in
Mechanical strength +	0,33	FFP3 ≤ 1 %	7.9.2 in range of the first and second protection class (FFP1,
Temperature conditioned	0.35		FFP2, FFP3)
	As received  Simulated wearing treatment  Mechanical strength + Temperature	in accordance with EN 13274-   7:2019	Condition in accordance with EN 13274- 7:2019 [%] Flow rate 95 l/min  0.09  As received 0.30 0.28 Simulated wearing treatment 0.32 Mechanical strength + Temperature 0.35  Tequirements in accordance with EN 149:2001+A1:2009  FFP1 $\leq$ 20 %  FFP2 $\leq$ 6 %  FFP3 $\leq$ 1 %

#### **Annex IIIB-Test Result:**

The test results obtained are given in the tables as follows:

1		suits obtained are given in	the tables as follows,		
	No. of Sample	Condition	Penetration of Paraffin Oil Mist in accordance with EN 13274-7:2019	Requirements in accordance with EN	Assessment of Test Result Conformity /
			[%]	149:2001+A1:2009	Nonconformity
			Flow rate 95 1/min		
	39		0,52		Passed
	40	As received	0,46		
	41		0,32	FFP1 ≤ 20 %	Filtering half masks fulfil
	4	Simulated wasning	0,44	10 10 10 10 10 = 100 10 10 10 10 10 10 10 10 10 10 10 10	the requirements of the
	5	Simulated wearing treatment	0,49	FFP2 ≤ 6 %	standard EN
	6	treatment	0,45		149:2001+A1:2009 given
	13	Mechanical strength +	0,56	FFP3 ≤ 1 %	in 7.9.2 in range of the first
	14	Temperature	0,61		and second protection
	15	conditioned	0,53		classes (FFP1, FFP2, FFP3)

Lab A + B





## 7.10 COMPATIBILITY WITH SKIN (EN 149:2001 + A1:2009 clause 8.4, 8.5)

Test Method: Described in Clause 8.4 and 8.5.

REQUIREMENT	RESULTS	COMMENT
Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	Pass	No irritation or any other adverse effect to health or sensitivity reported by the subjects during the practical performance and TIL tests.

Lab B

## 7.11 FLAMMABILITY (EN 149:2001 + A1:2009 clause 8.6)

Test Method: Described in Clause 8.6

REQUIREMENT	RESULTS	COMMENT
The material used shall not present a danger for the wearer and shall not be of highly flammable nature. When tested, the particle filtering half mask shall not burn or not to continue to burn 5s after removal from the flame.	Pass	Detail refer to Annex IV

## Annex IV-Test Result: The test results obtained are given in the tables as follows:

No. of Sample	Condition	Visual inspection	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
45	A	0,0 s	Filtering half mask	Passed
46	As received	0,1 s	shall not burn or not	Filtering half masks fulfil
21	Temperature	0,0 s	continue to burn for more than 5 s after	requirements of the standard EN 149:2001 +
22	conditioned	0,1 s	removal from the flame	A1:2009 given in 7.11

Lab B

## 7.12 CARBON DIOXIDE CONTENT OF THE INHALATION AIR (EN 149:2001 + A1:2009 clause 8.7)

Test Method: Described in Clause 8.7

REQUIREMENT	RESULTS	<u>COMMENT</u>
The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)	Pass	Detail refer to Annex V

#### Annex V-Test Result: The test results obtained are given in the tables as follows:

No. of Sample	Condition	CO <sub>2</sub> content of the inhalation air [%] by volume	An average CO <sub>2</sub> content of the inhalation air [%] by volume	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
26		0,53	o) voidine	CO <sub>2</sub> content of the	Passed
27	As received	0,52	0,53	inhalation air shall not exceed an	Filtering half masks fulfil requirements of the
28		0,54		average of 1,0% by volume	standard EN 149:2001 + A1:2009 given in 7.12

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TİC. LTD. ŞTİ.
Yukarı Dudullu-Ümraniye/İSTANBUL
Telefon: 0216 455 80 80 Faks: 0216 455 80 08
Sarigazi V.D. 892 025 8722



## 7.13 HEAD HARNESS (EN 149:2001 + A1:2009 clause 8.4, 8.5)

Test Method: Described in Clause 8.4, 8.5

REQUIREMENT	RESULTS	COMMENT
The head harness shall be designed so that the particle filtering half-mask can be donned and removed easily.	Pass	No problem with the head harness reported by the wearers during the practical performance test.
The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and capable of maintaining total inward leakage requirements for the device.	Pass	No problem with the head harness reported by the wearers during the practical performance test.

#### 7.14 FIELD OF VISION (EN 149:2001 + A1:2009 clause 8.4)

Test Method: Described in Clause 8.4

REQUIREMENT	RESULTS	COMMENT
The field of vision is acceptable if determined so in practical performance tests.	Pass	There were no adverse comments following practical performance tests.

Lab B

#### 7.15 EXHALATION VALVE (EN 149:2001 + A1:2009 clause 8.2, 8.3.4, 8.8, 8.9.1)

Test Method: Clause 8.2, 8.3.4, 8.8, 8.9.1

REQUIREMENT	RESULTS	COMMENT
A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	N/A	No exhalation valve in tested samples.
If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9	N/A	No exhalation valve in tested samples.
Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30s.	N/A	No exhalation valve in tested samples.
When the exhalation valve housing is attached to the face blank, it shall withstand axially a tensile force of 10N applied for 10s.	N/A	No exhalation valve in tested samples.

Lab -





## 7.16 BREATHING RESISTANCE (EN 149:2001 + A1:2009 clause 8.9)

Test Method: Described in Clause 8.9

	REQU	<u>IREMENT</u>	RESULTS	COMMENT	
Classification		rmitted resistance	e (mbar) Exhalation		Classified as FFP3
	30 l/min	95 l/min	160 l/min	Pass	Detail refer to Annex VIA-VIB
FFP1	0.6	2.1	3.0		
FFP2	0.7	2.4	3.0		
FFP3	1.0	3.0	3.0		

## Annex VIA-Test Result:

The test results obtained are given in the tables as follows;

Inhalation Resistance

No. of	Condition	Inhalation Resistance (mbar)					
Sample		Flow rate 30 l/min [mbar]	Requirements in accordance with EN 149:2001+A1:2009	Flow rate 95 l/min [mbar]	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity	
42		0,59	*	1,77			
43	As received	0,62		1,74			
44		0,57	FFP1 ≤ 0,60	1,76	FFP1 ≤ 2,10	Passed	
7	Simulated	0,59		1,83		Qualifies	
8	wearing	0,61	FFP2 ≤ 0,70	1,84	FFP2 ≤ 2,40	FFP1, FFP2,	
9	treatment	0,66		1,79		FFP3	
23	Tomorontono	0,70	FFP3 ≤ 1,0	1,84	FFP3 ≤ 3,00		
24	Temperature conditioned	0,69		1,82			
25	Conditioned	0,67		1,81		1 1 1 1 1 1 1 1 1 1	

**Exhalation Resistance** 

No. of Sample	Condition	Flow rate	Facing directly	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
42			2,70	2,68	2,58	2,73	2,69		
43	As received		2,75	2,65	2,54	2,68	2,63		
44			2,66	2,71	2,57	2,78	2,72	FFP1 ≤ 3,0	Passed
7	Simulated		2,71	2,75	2,65	2,72	2,67	1111 _ 5,0	Qualifies
8	wearing	1601/min	2,83	2,69	2,58	2,76	2,75	FFP2 ≤ 3,0	FFP1, FFP2,
9	treatment		2,74	2,66	2,55	2,69	2,68		FFP3
23	Т		2,63	2,74	2,68	2,65	2,66	FFP3 ≤ 3,0	<del></del>
24	Temperature conditioned		2,68	2,77	2,63	2,71	2,69		
25	conditioned		2,65	2,83	2,59	2,77	2,64		

Lab A





#### 7.17 CLOGGING (EN 149:2001 + A1:2009 clause 8.9, 8.10)

Test Method: Described in Clause 8.8, 8.10

REQUIREMENT	RESULTS	COMMENT
Valved particle filtering half masks: After clogging the inhalation resistances shall not exceed: FFP1:4mbar, FFP2:5mbar, FFP3:7mbar at 95L/min continuous flow. The exhalation resistance shall not exceed 3mbar at 160L/min continuous flow. Valveless particle filtering half masks: After clogging the inhalation resistances shall not exceed: FFP1:3mbar, FFP2:4mbar, FFP3:5mbar at 95L/min continuous flow	NAs	This is optional test and not desired by client.

Lab -

## 7.18 DEMOUNTABLE PARTS (EN 149:2001 + A1:2009 clause 8.2)

Test Method: Described in Clause 8.2

REQUIREMENT	RESULTS	COMMENT	
All demountable parts (if fitted) shall be readily connected and secured, where possible by hand	N/A	No demountable part.	

Lab -

Pass	Requirement satisfied.	
NCR	Requirement not satisfied. Refer to the "Result details" section for more information.	
NAs	Assessment not carried out.	
N/A	Requirement not applicable.	

## **LABORATORY INFORMATION**

Code	Laboratory Name	Competency Explanations						
Lab A	UNIVERSAL SERTIFIKASYON VE	Internal Laboratory Services of Notified Body						
GOZETIM HIZMETLERI TIC. LTD. STI.  GCNTR ULUSLARARASI  BELGELENDIRME, GOZETIM, EGITIM  VE DIS TICARET LIMITED SIRKETI  KOCAELI DILOVA SUBESI		Laboratory holds an accreditation by Turkish Accreditation Agency with number AB-1252-T according to EN ISO/IEC 17025:2017.						
•								
•	• Each test result given in this test report shown with the issuing laboratory code							





## Sample Photo



- End of Report -

