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CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163 - PPE - 687

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

[redacted]

are tested and evaluated according to

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition

Brand Name: SIGNO GROUP Model: Kids Mask
Filtering half mask
Total Inwards Leakage: Class – 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 **22 / 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

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

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CERTIFICATE OF CONFORMANCE

Certificate Nr: 2163-PPE-667/01

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

[redacted]

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles- Requirements, Testing, Marking

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2).This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

Product Definition

Model	Class			
		Serial Nr.	Date	Issuing NB Nr.
Kids Mask	FFP2NR	2163-PPE-667/01	22.05.2020	2163

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

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **22/05/2020** and will be valid for one year,until 21/05/2021 if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement..

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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: 20.05.2020
Report Number: 05-2020-T-087

CLIENT and SAMPLE INFORMATION

TEST OWNER	[redacted]		
ADDRESS			
SAMPLE DESCRIPTION	Folding type, particle filtering protective mask with ear loops (See end of test report for sample photo)		
BRAND NAME – MODEL	Kids Mask		
TESTING STANDARD	EN 149+A1:2009		
CASE NUMBER	CE-PPE-1981		
SAMPLE RECEIVE DATE	17.04.2020	TESTING START DATE	18.04.2020
DISINFECTION INSTRUCTION Uygun ise / If applicable	Not given, single use only		
NUMBER OF SAMPLES	50	SAMPLE IDs:	1 – 46
AS RECEIVED SAMPLE NO	26-46		
CONDITIONING SAMPLE NO	Simulated wearing treatment	1-2-3-4-5-6-7-8-9 (As Received)	
	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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Necip Fazil Bulvarı, Keyap Sitesi, E2 Blok, No:44/84
Yukarı Dudullu Ümraniye İSTANBUL
Telefon: 0216 455 80 80 Fax: 0216 455 80 08
Sertifika No: 852 [illegible]

Suat KAÇMAZ
Director

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1. *REPORT SUMMARY*

TEST STANDARD	*TEST NAME*	*RESULT*	*EVALUATION*
EN 149:2001 + A1:2009 clause 8.5 EN 13274-1:2001	Total Inward Leakage Testing	**Pass**	**FFP2**
EN 149:2001 + A1:2009 clause 8.11 EN 13274-7:2019	Penetration of Filter Material	**Pass**	**FFP2**
EN 149:2001 + A1:2009 clause 8.6 EN 13274-4:2001	Flammability Testing	**Pass**	**See result**
EN 149:2001 + A1:2009 clause 8.7 EN 13274-6:2001	Carbon Dioxide Content of The Inhalation Air Testing	**Pass**	**See result**
EN 149:2001 + A1:2009 clause 8.9 EN 13274-3:2001	Breathing Inhalation Resistance-30 l/min	**Pass**	**See results**
	Breathing Inhalation Resistance-95 l/min	**Pass**	**See results**
EN 149:2001 + A1:2009 clause 8.9 EN 13274-3:2001	Exhalation Resistance, flow rate 160 l/min	**Pass**	**See result**

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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 ± 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 ±1 °C.

a) for 24 h to a dry atmosphere of (70 ± 3) °C;

b) for 24 h to a temperature of (-30 ± 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

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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

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	2	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
Head harness comfort	2	0		
Security of fastenings	2	0		
Speech clearness	2	0		
Field of vision	2	0		
Materials compatibility with skin	2	0		

Lab B

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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.

Lab A

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 (%)	Mean (%)
1	31	A.R.	7,45	7,54	8,02	7,22	7,21	7,49
2	32	A.R.	6,92	7,65	8,32	**9,13**	8,03	**8,01**
3	33	A.R.	7,03	7,75	7,71	7,13	7,22	7,37
4	34	A.R.	7,18	8,14	7,15	8,03	7,76	7,65
5	35	A.R.	6,93	6,95	7,82	7,32	8,44	7,49
6	16	T.C.	7,78	7,92	8,19	7,41	7,65	7,79
7	17	T.C.	7,12	7,44	8,03	7,76	7,17	7,5
8	18	T.C.	6,75	7,32	7,72	7,34	7,82	7,39
9	19	T.C.	8,2	7,65	7,98	8,12	6,92	7,77
10	20	T.C.	8,12	7,83	7,38	7,56	7,44	7,67
All 50 individual exercise results were not greater than 11 % 9 of 10 individual wearer arithmetic means were not greater than 8 %								Pass (FFP2)

Lab B

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

Annex IIIA-Test Result:

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

No. of Sample	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
36	As received	4.54	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	**Passed** Filtering half masks fulfil the requirements of the standard EN 149:2001+A1:2009 given in 7.9.2 in range of the first and the second protection class (FFP1, FFP2)
37		5.86		
38		4.84		
1	Simulated wearing treatment	4.23		
2		5.19		
3		4.59		
10	Mechanical strength + Temperature conditioned	5.28		
11		5.08		
12		5.19		

Annex IIIB-Test Result:

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

No. of Sample	Condition	Penetration of Paraffin Oil Mist 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
39	As received	5.40	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Passed Filtering half masks fulfil the requirements of the standard EN 149:2001+A1:2009 given in 7.9.2 in range of the first and the second protection class (FFP1, FFP2)
40		4.73		
41		5.12		
4	Simulated wearing treatment	5.33		
5		4.93		
6		4.21		
13	Mechanical strength + Temperature conditioned	5.73		
14		5.26		
15		5.82		

Lab A + B

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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.

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	As received	1,1	Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame	Passed Filtering half masks fulfil requirements of the standard EN 149:2001 + A1:2009 given in 7.11
46		1,7		
21	Temperature conditioned	2,1		
22		1,5		

Lab B

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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	COMMENT
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_2 content of the inhalation air [%] by volume	An average CO_2 content of the inhalation air [%] by volume	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
26	As received	0,85	0,80	CO_2 content of the inhalation air shall not exceed an average of 1,0% by volume	Passed Filtering half masks fulfil requirements of the standard EN 149:2001 + A1:2009 given in 7.12
27		0,75			
28		0,80			

Lab B

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.

Lab B

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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 -

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

Test Method: Described in Clause 8.9

REQUIREMENT	RESULTS	COMMENT
Classification: Max permitted resistance (mbar) — Inhalation: 30 l/min / 95 l/min; Exhalation: 160 l/min FFP1: 0.6 / 2.1 / 3.0 FFP2: 0.7 / 2.4 / 3.0 FFP3: 1.0 / 3.0 / 3.0	Pass	Classified as FFP2 Detail refer to Annex VIA-VIB

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

Inhalation Resistance

No. of Sample	Condition	Inhalation Resistance (mbar)				
		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	As received	0,5	FFP1 ≤ 0,60 FFP2 ≤ 0,70 FFP3 ≤ 1,0	1,9	FFP1 ≤ 2,10 FFP2 ≤ 2,40 FFP3 ≤ 3,00	Passed
43		0,4		1,8		Passed
44		0,5		2,0		Passed
7	Simulated wearing treatment	0,4		2,2		Passed
8		0,5		1,9		Passed
9		0,4		2,1		Passed
23	Temperature conditioned	0,5		2,3		Passed
24		0,6		2,0		Passed
25		0,5		2,1		Passed

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 (mbar)	Assessment Test Result Conformity Nonconform
42	As received	160l/min	2,5	2,8	2,7	2,7	2,7	FFP1 ≤ 3,0 FFP2 ≤ 3,0 FFP3 ≤ 3,0	Passed
43			2,8	2,7	2,6	2,6	2,7		Passed
44			2,7	2,6	2,7	2,7	2,6		Passed
7	Simulated wearing treatment		2,6	2,8	2,8	2,7	2,8		Passed
8			2,6	2,6	2,7	2,8	2,8		Passed
9			2,7	2,7	2,7	2,7	2,7		Passed
23	Temperature conditioned		2,7	2,7	2,8	2,9	2,9		Passed
24			2,9	2,7	2,9	2,8	2,8		Passed
25			2,7	2,6	2,9	2,9	2,8		Passed

Lab A

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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 GOZETIM HIZMETLERI TIC. LTD. STI.	Internal Laboratory Services of Notified Body
Lab B	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.

- The laboratories are contracted bodies with UNIVERSAL CERTIFICATION and the technical competence of the laboratories is also under supervision / assessment of UNIVERSAL CERTIFICATION based on the provisions of EN ISO/IEC 17065 Requirements for bodies certifying products, processes and services standard.
- Each test result given in this test report shown with the issuing laboratory code.

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Sample Photo

- End of Report -

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TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 22.05.2020 / 2163-KKD-651

[redacted]

This report is for the, given above, manufacturer prepared according to the test results obtained by UNIVERSAL CERTIFICATION for the product dated 20.05.2020 with ID 05-2020-T-087 based on EN 149: 2001 + A1: 2009 standard, The technical file of the manufacturer, and risk evaluation against the essential health safety requirements and the test report evaluated for their relation with Essential Requirements of Personel Protective Equipment Regulation and found to be appropriate.

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

Product Description: Particle Filtering Half Mask
Classification: FFP2
Trademark: LORE
Model: LZY03

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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 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

3.10.2. Protection against cutaneous and ocular contact

PPE intended to prevent the surface contact of all or part of the body with substances and mixtures which are hazardous to health or with harmful biological agents must be capable of preventing the penetration or permeation of such substances and mixtures and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.

To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear.

Where, by virtue of their nature and the foreseeable conditions of their use, certain substances and mixtures which are hazardous to health or harmful biological agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, in the absence of the names, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.

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Technical Assessment of EN 149: 2001 + A1: 2009 Standard and other Standards it refers to, Clauses Corresponding to the (EU) 2016/425 Directive

Conforming to EN 149:2001 + A1:2009 Standard Requirements	
Article 5	**Classification :** Particle Filtering Half Mask Total Inward Leakage: Classification – FFP2
Article 7.4	**Packing:** Particle filtering half masks are packaged to protect them from contamination before use and with cardboard boxes to prevent mechanical damage.
Article 7.5	**Material:** Materials used in particle filtering half masks, according to the simulated wearing treatment and temperature conditioning reports; It is understood withstand handling and wear over the period for which the particle filtering half mask is designed to be used, suffered mechanical failure of the facepiece or straps. any material from the filter media released by the air flow through the filter has not constitute a hazard or nuisance for the wearer.
Article 7.6	**Cleaning and Disinfection:** Particle filtering half mask is not designed to be as re-usable.
Article 7.7	**Practical Performance :** Assessed Elements: 1.The face piece fitting; 2.Head harness comfort; 3.Security of fastenings; 4.Speech clearness; 5.Field of vision; 6.Materials compatibility with skin Positive: 2; 2; 2; 2; 2; 2 Negative: 0; 0; 0; 0; 0; 0 Requirements in accordance with EN 149:2001 + A1:2009 and Result: Positive results should be obtained from the performance tests related to the implementation under real conditions. **No imperfections** **Conditioning :** (A.R.) As Received, original
Article 7.8	**Finish of Parts:** Particle filtering half masks, which are likely to come into contact with the user, do not have sharp edges and do not contain burrs.
Article 7.9.1	**Total Inward Leakage:**

Test Subject	No.of sample	Condition	1.Walk	Head left /right	Head up /down	Speech	2. Walk	Average
1	31	A.R	7,45	7,54	8,02	7,22	7,21	7,49
2	32	A.R	6,92	7,65	8,32	9,13	8,03	8,01
3	33	A.R	7,03	7,75	7,71	7,13	7,22	7,37
4	34	A.R	7,18	8,14	7,15	8,03	7,76	7,65
5	35	A.R	6,93	6,95	7,82	7,32	8,44	7,49
6	16	T.C.	7,78	7,92	8,19	7,41	7,65	7,79
7	17	T.C.	7,12	7,44	8,03	7,76	7,17	7,5
8	18	T.C.	6,75	7,32	7,72	7,34	7,82	7,39
9	19	T.C.	8,2	7,65	7,98	8,12	6,92	7,77
10	20	T.C.	8,12	7,83	7,38	7,56	7,44	7,67
Average			7,35	7,62	7,83	7,7	7,57	7,61
Min			6,75	6,95	7,15	7,13	6,92	7,37
Max			8,2	8,14	8,32	9,13	8,44	8,01

Conditioning : (A.R.) As Received, original
(T.C.) Temperature conditioning

Results P (%) Leakage Value

Results meet with FFP2 requirements

Article 7.9.2	**Penetration of filter material:** Sodium Chloride Testing Condition: (A.R.); (A.R.); (A.R.); (S.W.); (S.W.); (S.W.); (M.S. T.C.); (M.S. T.C.); (M.S. T.C.) No. of Sample: 36; 37; 38; 1; 2; 3; 10; 11; 12 Sodium Chloride Testing 95 L/min max (%): 4,54; 5,86; 4,84; 4,23; 5,19; 4,59; 5,28; 5,08; 5,19 Requirements in accordance with EN 149:2001 + A1:2009: FFP1 ≤ 20 %; FFP2 ≤ 6 %; FFP3 ≤ 1 % Result: 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)** **Conditioning :** (M.S.) Mechanical Strength (T.C.) Temperature Conditioning (A.R.) As Received, original (S.W.) Simulated wearing treatment 95 L/min = 1,6 $dm^3.sn^{-1}$

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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.)	39	5,40		
(A.R.)	40	4,73		
(A.R.)	41	5,12	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	5,33		
(S.W.)	5	4,93	FFP2 ≤ 6 %	
(S.W.)	6	4,21		
(M.S. T.C.)	13	5,73	FFP3 ≤ 1 %	
(M.S. T.C.)	14	5,26		
(M.S. T.C.)	15	5,82		

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.)	45	1,1	Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame	**Passed**
(A.R.)	46	1,7		
(T.C.)	21	2,1		Filtering half masks fulfill requirements of the standard
(T.C.)	22	1,5		

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.)	26	0,85	0,80	CO_2 content of the inhalation air shall not exceed an average of 1,0% by volume	**Passed**
(A.R.)	27	0,75			
(A.R.)	28	0,80			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.)	42	0,5	FFP1 ≤ 0,6	1,9	FFP1 ≤ 2,1	**Passed**
(A.R.)	43	0,4		1,8		
(A.R.)	44	0,5		2,0		
(S.W.)	7	0,4	FFP2 ≤ 0,7	2,2	FFP2 ≤ 2,4	
(S.W.)	8	0,5		1,9		
(S.W.)	9	0,4	FFP3 ≤ 1,0	2,1	FFP3 ≤ 3,0	
(T.C.)	23	0,5		2,3		
(T.C.)	24	0,6		2,0		
(T.C.)	25	0,5		2,1		

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

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	As received	160 l/min	2,5	2,8	2,7	2,7	2,7	FFP1 ≤ 3,0 FFP2 ≤ 3,0 FFP3 ≤ 3,0	Passed
43			2,8	2,7	2,6	2,6	2,7		Passed
44			2,7	2,6	2,7	2,7	2,6		Passed
7	Simulated wearing treatment		2,6	2,8	2,8	2,7	2,8		Passed
8			2,6	2,6	2,7	2,8	2,8		Passed
9			2,7	2,7	2,7	2,7	2,7		Passed
23	Temperature conditioned		2,7	2,7	2,8	2,9	2,9		Passed
24			2,9	2,7	2,9	2,8	2,8		Passed
25			2,7	2,6	2,9	2,9	2,8		Passed

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 templates prepared by manufacturer to be used on 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 in the corresponding templates and documents in the technical file.

PREPARED BY	APPROVED BY
Osman CAMCI PPE Expert	**Suat KAÇMAZ** General Manager

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