Occupational Safety Research Institute, v.v.i.
Notified Body 1024
Jeruzalémská 1283/9, CZ - 110 00 Praha 1

FINAL REPORT ON CERTIFICATION *
No. 1024/ZZ-106/2020

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I. Source data

Name:	**Protective half mask**	
Type:	**PM-1**	
PPE category:	III. according to Regulation (EU) 2016/425 Annex I	
Manufacturer:	TRAYAL Corporation., Parunovaćka 18 V, 37 000, Krusevać, Serbia	
Application:	S-763/2020	dated: 14. 10. 2020
Contract:	092/2020	dated: 23. 11. 2020
Certified by:	Ing. L. Zavřel	
Date of report issue:	26. 11. 2020	

Výzkumný ústav bezpečnosti práce, v. v. i. Akreditovaná zkušební laboratoř č. 1040 VÚBP Jeruzalémská 1283/9, 110 00 Praha 1

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signature

The product was certified according to Regulation (EU) 2016/425, Module B. The conformity of the product with the essential requirements of this Regulation was carried out in the form of EU type examination.

Distribution list: 1. manufacturer
2. laboratory archive
3. secretariat VÚBP-OS 1024

*This Final report has been issued in Czech and English versions. Both versions have the same validity.

II. Basic information

1. Description of product function and use

Protective half mask **PM-1** with one inhalation and one exhalation valve in combination with suitable filter protects the user's respiratory system against harmful substances in the air in accordance with the information supplied by the manufacturer.

2. Sample withdrawal - taking

Samples of the PM-1 half mask for laboratory tests were supplied by the manufacturer on 21. 9. and 21. 10. 2020 in the number of 5 and 3 pieces. The samples were registered in the Laboratory Register under numbers 7935 - 7939 and 8484 - 8486.

III. List of submitted technical documentation

According to Regulation (EU) 2016/425 Annex III.

a)	a complete description of the PPE and of its intended use	+
b)	an assessment of the risks against which the PPE is intended to protect	+
c)	a list of the essential health and safety requirements that are applicable to the PPE	+
d)	design and manufacturing drawings and schemes of the PPE and of its components, sub-assemblies and circuits	+
e)	the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (d) and of the operation of the PPE	+
f)	the references of the harmonised standards referred to in Article 14 that have been applied for the design and manufacture of the PPE. In the event of partial application of harmonised standards, the documentation shall specify the parts which have been applied	+
g)	where harmonised standards have not been applied or have been only partially applied, descriptions of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements	0
h)	the results of the design calculations, inspections and examinations carried out to verify the conformity of the PPE with the applicable essential health and safety requirements	+
i)	reports on the tests carried out to verify the conformity of the PPE with the applicable essential health and safety requirements and, where appropriate, to establish the relevant protection class	+
j)	a description of the means used by the manufacturer during the production of the PPE to ensure the conformity of the PPE produced with the design specifications	+
k)	a copy of the manufacturer's instructions and information set out in point 1.4 of Annex II	+
l)	for 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	0
m)	for PPE produced in series where each item is adapted to fit an individual user, a description of the measures to be taken by the manufacturer during the fitting and production process to ensure that each item of PPE complies with the approved type	0

and with the applicable essential health and safety requirements	

Evaluation: + available, range is satisfactory; - requirement not fulfilled; 0 not applicable

The submitted technical documentation was found to be complete according to Regulation (EU) 2016/425 ANNEX III and it has been adequate for the assessment of the conformity with the technical requirements mentioned in this Regulation.

IV. Testing

The tests were performed in accordance with:
EN 140:1998, EN 140:1998/AC: 1999 Respiratory protective devices - Half masks and quarter masks - Requirements, testing, marking (idt. ČSN EN 140:1999, ČSN EN 140 Oprava 1:2000)
Notice: Report clause numbering is consistent with the above-mentioned standard numbering.

6.3 Visual inspection
Requirement: The visual inspection shall include the marking and Information supplied by the manufacturer.
Evaluation: Samples have satisfied the requirement

6.4 Materials
Requirement: The use of aluminium, magnesium and titanium or alloys containing such proportions of these metals as will, on impact, give rise to frictional sparks capable of igniting flammable gas mixtures for exposed parts, i.e. those which may be subjected to impact during use of the apparatus shall be restricted to a minimum.
Evaluation: Samples have satisfied the requirement

6.5. Resistance to temperature
Requirement: Following the conditioning in accordance with 7.2 and after being allowed to return to ambient temperature the facepiece shall show no appreciable deformation and any incorporated connector to prEN 148-1 shall be gauged and shall comply with the appropriate standard.
After this test the facepiece shall meet the requirements for inward leakage as specified in 6.16.
Discovered: The half mask lasted without visible change in temperature cycle exposure.
Evaluation: Samples have satisfied the requirement

6.6 Flammability
Requirement: Parts of the facepiece that might be exposed to a flame during use shall either not burn or not continue to burn for more than 5 s after removal from the flame It is not required that the facepiece still has to be useable after the test..
Discovered: No material half mask during test flammability no burn, no glow, no drip. After passing through the flame no part of the half mask does not continue to burn.
Evaluation: Samples have satisfied the requirement

6.7 Cleaning and disinfecting
Requirement: The materials used shall withstand the cleaning and disinfecting agents and procedures as recommended by the manufacturer.
Discovered: The half mask material is resistant to common cleaning and disinfection agents (detergents, ethanol).
Evaluation: Samples have satisfied the requirement

6.8 Demountable parts
Requirement: All demountable connections shall be readily connected and secured, where possible by hand. Any means of sealing used shall be retained in position when the connection is disconnected during normal maintenance.
Evaluation: Samples have satisfied the requirement

6.9 Replaceable components

Requirement: Unless integral with the half mask or quarter mask the following components (if fitted) shall be replaceable: Head harness, connector(s), inhalation and exhalation valves.
Evaluation: Samples have satisfied the requirement

6.10 Head harness
6.10.1 Requirement: The head harness shall be designed so that the facepiece can be donned and removed easily.
6.10.2 Requirement: The head harness shall be adjustable or self-adjusting and shall hold the facepiece firmly and comfortably in position.
6.10.3 Requirement: Each strap of the head harness, buckles and other adjusting means shall withstand a pull of 50 N applied for 10 s in the direction of pulling when the facepiece is donned. No breaks or sliding of the straps shall occur. The requirement applies to the buckles and attachment lugs as well as to the straps.
Discovered: All parts of the half mask head harness system withstood a pull of 50 N for 10 seconds.
Evaluation: Samples have satisfied the requirement

6.11 Connector
6.11.1 Requirement: A facepiece shall not have more than one thread connection to prEN 148-1.
6.11.1.1 Requirement: A facepiece shall not have more than one thread connection to prEN 148-1. If more than one connector is fitted the design of the facepiece or of the remainder of the equipment shall be such that the use of different types or combinations of respiratory protective devices does not present a risk.
6.11.1.2 Requirement**:** If any other screw thread is used it shall not be possible to connect it directly to the thread to prEN 148-1.
6.11.1.3 Requirement: Half masks and quarter masks shall not be equipped with a thread connection to prEN 148-2.
6.11.2 Requirement**:** The connection between the faceblank and the connector shall be sufficiently robust to withstand axially a tensile force of 50 N.
6.11.3 Requirement: Correct and reliable connection between facepiece and other parts of the equipment shall be assured.
Discovered: The half mask is equipped with one thread according to EN 148-1. The connection between the faceblank and the connector withstood 50 N axial force for 10 seconds.
Evaluation: Samples have satisfied the requirement

6.12 Inhalation valves and exhalation valves
6.12.1 General
Requirement: Valve assemblies shall be such that they can be readily maintained and correctly replaced. It shall not be possible to fit an exhalation valve assembly into the Inspiratory circuit or an inhalation valve assembly into the exhalation circuit. Inhalation and exhalation valve assemblies, sub-assemblies and piece parts that are by the manufacturer designed to be identical, are acceptable. Differently designed inhalation and exhalation valves are acceptable if a precise and comprehensible description is given in the information manual supplied by the manufacturer. The description in the information manual supplied by the manufacturer should be supported by illustrations (photographs, drawings) on how to assemble the unit correctly. To enable correct assembly, the parts have to be precisely and comprehensibly described or marked. An appropriate method of checking correct assembly shall be described, e.g. visual inspection; check by the wearer: test by maintenance personnel etc.
6.12.2 Inhalation valve
6.12.2.1 Requirement: The facepiece should preferably be provided with one or more inhalation valves). If a thread connection to prEN 148-1 is used, an inhalation valve shall be incorporated in the facepiece. Where the facepiece is intended to be used with filters it shall be provided with an integral inhalation valve, if there is no valve in the filter.
6.12.2.2 Requirement: Inhalation valves shall function correctly in all orientations and shall meet the requirements of 6.15.
Evaluation: Samples have satisfied the requirement

6.12.3 Exhalation valve

6.12.3.1 Requirement: Exhalation valves shall function correctly in all orientations and shall meet the requirements of 6.15.

6.12.3.2 Requirement: The facepiece shall have at least one exhalation valve or appropriate means to allow the escape of exhaled air and, where applicable, any excess air delivered from a supplied air source.

6.12.3.3 Requirement**:** Exhalation valves (if fitted) shall be protected against or be resistant to dirt and mechanical damage. They may be shrouded or include any other device that may he necessary to comply with 6.16.

6.12.3.4 Requirement: Exhalation valves shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s and meet the requirements of 6.15.

6.12.4 Requirement: When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 50 N applied for 1 0 s.

Discovered: The exhalation valve operates correctly even after a continuous exhalation flow of 300 l/min applied for 30 s. The exhalation valve housing withstood an axial force of 50 N for 10 seconds.

Evaluation: Samples have satisfied the requirement

6.13 Compatibility with skin

Requirement: Materials that can 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.

Discovered: According to the manufacturer's declaration the materials used are not harmful to health.

Evaluation: Samples have satisfied the requirement

6.14 Carbon dioxide content of inhalation air

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume).

Discovered:

sample	condition	Average CO_2 concentration% vol.
8485	AR	0,60
7938	TC	0,64

Note: TC - temperature conditioning
AR - as received

Evaluation: Samples have satisfied the requirement

6.15 Breathing resistance

Requirement: The breathing resistance of the facepiece shall not exceed 2,0 mbar for inhalation and 3,0 mbar for exhalation when tested with a breathing machine (25 cycles/min, 2,0 I/stroke) or a continuous flow of 160 I/min. The inhalation resistance shall not exceed 0,5 mbar at 30 I/min continuous flow and 1,3 mbar at 95 I/min continuous flow.

Discovered:

Inhalation resistance

condition	AR	resistance (Pa)				
		position				
sample	flow (l/min)	ahead	down	up	left	right
7935	30	44	36	41	38	37
	95	113	114	114	113	113
	160	197	199	198	198	197

condition	TC	resistance (Pa)				
		position				
sample	flow (l/min)	ahead	down	up	left	right
7936	30	40	35	38	37	37
	95	102	105	103	103	104
	160	182	185	184	183	183

Exhalation resistance

flow 160 l/min		resistance (Pa)				
		position				
sample	condition	ahead	down	up	left	right
7935	AR	249	255	250	251	250

flow 160 l/min		resistance (Pa)				
		position				
sample	condition	ahead	down	up	left	right
7936	TC	241	245	243	242	242

Evaluation: Samples have satisfied the requirement

6.16 Inward leakage

Requirement: When the facepieces are fitted in accordance with the information supplied by the manufacturer, at least 46 out of the 50 individual results for the inward leakage over each of the exercise periods as defined in 7.13,1.3 (i.e. 10 subjects x 5 exercise periods) shall be not greater than 5 % and, in addition, at least 8 out of the 10 individual wearer arithmetic means (10 subjects) for the inward leakage; averaged over all exercise periods shall be not greater than 2 %.

Discovered:

test subject		sample	condition	exercise					average
				a)	b)	c)	d)	e)	
1	ETi	7937	TC	0,793	2,390	0,338	0,239	0,081	**0,768**
2	SCh	7937	TC	0,423	0,344	0,513	0,082	0,044	**0,281**
3	FNe	7937	TC	0,266	0,172	0,183	0,361	0,168	**0,230**
4	ZKo	7937	TC	1,666	2,543	2,035	1,062	0,166	**1,494**
5	MDb	7937	TC	0,520	0,407	0,508	0,186	0,116	**0,347**
6	IHe	8484	AR	1,767	2,203	1,182	0,443	2,931	**1,705**
7	MSk	8484	AR	2,729	0,455	1,960	0,470	0,664	**1,256**
8	JFo	8484	AR	0,048	0,051	0,082	0,078	0,056	**0,063**
9	JT	8484	AR	0,025	0,021	0,021	0,034	0,030	**0,026**
10	PM	8484	AR	0,001	0,000	0,002	0,002	0,001	**0,001**
average				0,824	0,859	0,682	0,296	0,426	**0,617**

Exercises: a) walk only
b) head side to side
c) head up and down
d) reciting an alphabet
e) walk only

Description of test persons faces:

test person		lenght mm	width mm	depth mm	mouth mm
1	ETi	118	116	129	54
2	SCh	102	111	119	57
3	FNe	123	131	141	48
4	ZKo	116	129	126	62
5	MDb	123	117	125	55
6	IHe	114	131	126	52
7	MSk	106	126	116	52
8	JFo	114	122	123	56
9	JT	121	126	138	54
10	PM	113	129	145	55

Evaluation: Samples have satisfied the requirement

6.17 Field of vision
Requirement: The field of vision shall be subjectively assessed for acceptability.
Discovered:
Evaluation: Samples have satisfied the requirement

6.18 Practical performance
Requirement: The complete apparatus shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this European Standard. In addition tc the tests described in this European Standard details of practical performance tests for breathing apparatus are given in the relevant European Standard. Where a half mask or quarter mask is to be used for filtering devices testing shall be in accordance with 7.14.
Discovered: The test subjects had no major negative comments.
Evaluation: Samples have satisfied the requirement

V. Conformity assessment to the essential requirements

The examination of the manufacturer's technical file, the tests and the evaluations have shown that the submitted model has been designed and manufactured

in accordance with the essential requirements of Regulation (EU) 2016/425,

on personal protective equipment,

the following harmonized standards have been used during the assessment: EN 140:1998.

VI. List of documents necessary for the final report elaboration

1. Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment and repealing Council Directive 89/686/EEC
2. Application for EU type examination no. S-763/2020 dated 14. 10. 2020
3. Contract about EU type examination no. 092/2020 dated 23. 11. 2020
4. Test report no. 720/2020 dated 11. 11. 2020
5. Test report no. 739/2020 dated 23. 11. 2020
6. Declarations of manufacturer, technical documentation
7. EN 140:1998, EN 140:1998/AC:1999 Respiratory protective devices - Half masks and quarter masks - Requirements, testing, marking (idt. EN 140:1999, EN 140 Oprava 1:2000)