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-020/2021

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I. Source data

Name:	**Transparent respirator**	
Type:	**PR21**	
PPE category:	III. according to Regulation (EU) 2016/425 Annex I	
Manufacturer:	Peter Knobloch, Malý Rohozec 1, 511 01 Turnov, Czech Republic	
Application:	S-762/2020	dated: 13. 10. 2020
Contract:	009/2021	dated: 8. 2. 2021
Certified by:	Ing. L. Zavřel	
Date of report issue:	25. 2. 2021	

Výzkumný ústav bezpečnosti práce, v.v.i. Oznámený subjekt 1024 - Notified Body 1024 VÚBP v.v.i. Jeruzalémská 1283/9 Praha 1 Czech Republic

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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

Transparent respirator PR21 with two inhalation and one exhalation valve in combination with two particle filters FPR21 P2 R protects the user's respiratory system against solid and liquid aerosols in the air in accordance with the information supplied by the manufacturer.

Transparent respirator PR21 is made in black and green colour.

Upon agreement with the manufacturer, the product was considered a quarter mask in the sense of EN 140, which will be in accordance with the manual used only with the supplied filters FPR21, preferably as protection against COVID-19, where the level of protection FFP2 according to EN 149+A1 is considered sufficient.

2. Sample withdrawal - taking

Samples of the PR21 quarter mask with FPR21 filters for laboratory tests were supplied by the manufacturer on 13 October, 7 December 2020 and 7 January 2021 in a total of 7 quarter masks and 17 filters. The samples were registered in the Laboratory Register under numbers 8359 - 8360 (PR21 quarter masks), 9890 - 9906 (FPR21 filters) and 108 - 112 (PR21 quarter masks).

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	0
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 and with the applicable essential health and safety requirements	0

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)
EN 143:2000, EN 143:2000/A1:2006 Respiratory protective devices. Particle filters. Requirements, testing, marking (idt. ČSN EN 143:2001, Změna A1:2006)

Notice: Report clause numbering is consistent with the above-mentioned standard numbering.

according to EN 140

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 quarte rmask 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 quarter 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 quarter 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 quarter mask is equipped with two special insertion chambers with inhalation valves for particle filters. The connection between the faceblank and the insertion chambers 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.
8359	TC	1,00
8360	AR	0,98

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 l/stroke) or a continuous flow of 160 l/min. The inhalation resistance shall not exceed 0,5 mbar at 30 l/min continuous flow and 1,3 mbar at 95 l/min continuous flow.

Discovered:

Inhalation resistance

condition	**AR**	**resistance (Pa)**				
		position				
sample	**flow (l/min)**	ahead	down	up	left	right
8359	30	11	10	11	10	12
	95	33	30	32	32	32
	160	55	54	55	52	53

condition	**TC**	**resistance (Pa)**				
		position				
sample	**flow (l/min)**	ahead	down	up	left	right
111	30	15	12	14	13	12
	95	38	32	35	32	33
	160	57	48	54	55	56

Exhalation resistance

flow 160 l/min		**resistance (Pa)**				
		position				
sample	**condition**	ahead	down	up	left	right
8359	TC	121	119	120	120	120

flow 160 l/min		**resistance (Pa)**				
		position				
sample	**condition**	ahead	down	up	left	right
111	AR	59	58	60	59	59

Evaluation: Samples have satisfied the requirement

6.16 Inward leakage

The PR21 transparent respirator will be used exclusively with FPR21 P2 R filters. The total inward leakage test was assessed by the **EN 149:2001+A1:2009 standard as a filtering half mask to protect against particles class FFP2**.

Requirement: The laboratory tests shall indicate that the particle filtering half mask can be used by the wearer to protect with high probability against the potential hazard to be expected. The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration. For particle filtering half masks at least 46 out of the 50 individual exercise results for total inward leakage shall not be greater than 11 % for class FFP2 and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall not be greater than 8 % for class FFP2.

Discovered:

Measured with two FPR21 P2 R particle filters

test subject		sample	condition	exercise					average
				a)	b)	c)	d)	e)	
1	JP	108	TC	9,980	8,596	3,616	5,007	3,889	**6,217**
2	LZ	108	TC	4,984	4,327	4,334	4,995	3,860	**4,500**
3	MDo	108	TC	2,992	2,933	3,746	6,155	3,933	**3,952**
4	JFo	108	TC	4,880	4,278	4,130	7,486	4,011	**4,957**
5	PM	108	TC	3,276	2,726	2,960	4,222	5,221	**3,681**
6	JT	110	AR	4,608	2,070	5,111	10,513	6,067	**5,674**
7	MSk	110	AR	4,767	5,291	5,558	8,168	4,217	**5,600**
8	IHe	110	AR	2,940	3,484	3,031	7,318	3,420	**4,039**
9	ETi	110	AR	2,892	4,922	4,454	1,995	4,129	**3,678**
10	JBo	110	AR	5,598	5,496	6,242	6,501	5,299	**5,827**
average				4,692	4,412	4,318	6,236	4,405	**4,813**

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.
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 quarter mask slightly restricts the field of vision and can press on the nose. No other negative comments on the tested quarter masks were recorded.
Evaluation: Samples have satisfied the requirement

according to EN 140

7.3 Visual inspection
Requirement: A visual inspection of the filters shall be carried out and the appropriate results reported. The visual inspection includes marking and informations supplied by the manufacturer.
Evaluation: Samples have satisfied the requirement

7.4 Connection
Requirement:The connection between filter(s) and facepiece or other device(s) with which' it is intended to be used shall be robust and leaktight.The connection between filter and facepiece may be achieved by a permanent or special connector or by a screw thread including a thread conforming to EN 148-1. Threads conforming to EN 148-2 or EN 148-3 shall not be used. If the filter is designated to be used on a multiple filter facepiece or has any other thread, it shall not be possible to connect it to a thread conforming to EN 148-1, EN 148-2 or EN 148-3. The filter shall be readily replaceable without use of special tools and shall be designed or marked to prevent incorrect assembly.
Discovered: The filter is of the cubic type and is placed in the housing of the quarter mask. Connection is robust and leaktight.
Evaluation: Samples have satisfied the requirement

7.5 Mass
Requirement: The maximum mass of filter(s) designated to be used directly connected to a half mask is 300 g.The maximum mass of filter(s) designated to be used directly connected to a full face mask is 500 g.
Discovered:

sample	conditioning	mass (g)
9901	MS+TC	14,9
9902	MS+TC	14,9
9896	MS	14,6
9897	MS	14,7

Notice: MS - mechanical strength
Evaluation: Samples have satisfied the requirement

7.6 Multiple filters
Requirement: Where filtering devices are designed to use more than one filter (i.e. multiple filter device), through which the flow is proportioned, all requirements given in this European Standard are to be met by the complete set of filters (e.g. the total mass of a filter set designated to be used directly connected to a half mask shall not exceed 300 g). If, however, it is possible that the single filter of a multiple filter device may be used alone, then the requirements at the full flow rate for the tests, as stated in this European Standard, shall be met. In the information supplied by the manufacturer all necessary information on how to use multiple filters shall be given.
Evaluation: Samples have satisfied the requirement

7.7 Material
Requirement: The filter shall be made of suitable material to withstand normal usage and exposures to those temperatures, humidity and corrosive environments that are likely to be encountered. Internally it shall withstand corrosion by the filtering media. Any material of the filter media or any gaseous products that may be released by the air flow through the filter shall not be known to constitute a hazard or nuisance for the wearer.
Evaluation: Samples have satisfied the requirement

7.8 Packaging
Requirement: Filters shall be offered for sale packaged in such a way that they are protected against mechanical damage or visual contamination before use. Where appropriate, filters shall be factory sealed to protect the filter media against environmental influences and in such a way that the breaking of the factory sealing can be identified.

Evaluation: Samples have satisfied the requirement

7.9 Mechanical strength (M.S.)
Requirement: Filters shall be subjected to the mechanical strength test when required by the relevant clauses of this standard. After the treatment the filters shall show no mechanical defect and shall meet the requirement of the relevant clauses.
Discovered: Filters show no mechanical defects after the test.
Evaluation: Samples have satisfied the requirement

7.10 Temperature conditioning (T.C.)
Requirement: Filters shall be subjected to the temperature conditioning test when required by the relevant clauses of this standard. After the treatment the filters shall show no signs of damage and shall meet the requirement of the relevant clauses.
Discovered: Filters show no signs of damage after the test.
Evaluation: Samples have satisfied the requirement

7.11 Breathing resistance
Requirement: The breathing resistance shall not exceed for class P2 70 Pa at flow of 15 l/min and 240 Pa at flow of 47,5 l/min.
Discovered:

sample	conditioning	breathing resistance Pa	
		flow 15 l/min	flow 47,5 l/min
9896	MS	26	84
9897	MS	26	90
9898	MS+TC	23	71
9899	MS+TC	18	63

Evaluation: Samples have satisfied the requirement

7.12 Filter penetration
Requirement: The penetration of sodium chloride aerosol and paraffin oil aerosol shall not exceed for class P2 the value of 6 %.
Discovered:

initial penetration of NaCl aerosol

sample	conditioning	penetration %
9898	MS+TC	0,73
9890	MS+TC	1,36
9900	MS+TC	1,38

the highest measured value of penetration of NaCl aerosol

sample	conditioning	penetration %	time of the highest measured value in minutes
9898	MS+TC	0,73	3
9890	MS+TC	1,36	3
9900	MS+TC	1,38	3

penetration of NaCl aerosol after storage

sample	conditioning	penetration %
9898	MS+TC	0,72
9890	MS+TC	1,11
9900	MS+TC	0,83

initial penetration of paraffin oil aerosol

sample	conditioning	penetration %
9893	MS+TC	0,78
9894	MS+TC	0,54
9895	MS+TC	0,49

penetration of paraffin oil aerosol after exposition 120 mg oil

sample	conditioning	penetration %
9893	MS+TC	0,75
9894	MS+TC	0,49
9895	MS+TC	0,43

penetration of paraffin oil aerosol after storage

sample	conditioning	penetration %
9893	MS+TC	0,76
9894	MS+TC	0,51
9895	MS+TC	0,46

Evaluation: Samples have satisfied the requirement

7.13 Clogging

7.13.2 Filter penetration

Requirement: The filter penetration requirements of 7.12 shall be satisfied for each test aerosol before and after the clogging test with dolomite dust - the penetration shall not exceed for class P2 the value of 6 %.

Discovered:

initial penetration of NaCl aerosol after clogging

sample	conditioning	penetration %
9896	MS	0,44
9901	MS+TC	0,56
9902	MS+TC	0,59

initial penetration of paraffin oil aerosol after clogging

sample	conditioning	penetration %
9891	MS+TC	0,42
9892	MS+TC	0,42
9897	MS	0,3

Evaluation: Samples have satisfied the requirement

7.13.3 Breathing resistance

Requirement: The breathing resistance after clogging shall not exceed for class P2 the value of 500 Pa.

Discovered:

flow		**47,5 (l/min)**
sample	**conditionig**	**resistance (Pa)**
9896	MS	138
9897	MS	136
9901	MS+TC	124
9902	MS+TC	137

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, EN 140:1998/AC:1999; EN 149:2001+A1:2009 and EN 143:2000, EN 143:2000/A1:2006.

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-762/2020 dated 13. 10. 2020
3. Contract about EU type examination no. 009/2021 dated 8. 2. 2021
4. Test report no. 019/2021 dated 25. 1. 2021
5. Test report no. 046/2021 dated 8. 2. 2021
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)
8. EN 149:2001+A1:2009 Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking (idt. ČSN EN 149:2002+A1:2009, ČSN EN 149+A1 OPRAVA 1:2018)
9. EN 143:2000, EN 143:2000/A1:2006 Respiratory protective devices. Particle filters. Requirements, testing, marking (idt. ČSN EN 143:2001, Změna A1:2006)