



FINAL REPORT ON CERTIFICATION *

No. 1024/ZZ-015/2021

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I. Source data

Name: **Respirator face mask**

Type: **R-DP-R-FFP2-01**

PPE category: III. according to Regulation (EU) 2016/425 Annex I

Manufacturer: ROYAX s.r.o., Obchodní 107, 251 01 Čestlice, Czech Republic

Application: S-810/2020 dated: 10. 11. 2020

Contract: 012/2021 dated: 5. 2. 2021

Certified by: Ing. L. Zavřel



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signature

Date of report issue: 12. 2. 2021

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

Respirator face mask **R-DP-R-FFP2-01** FFP2 NR provides the protection of the respiratory system of a user against solid and liquid aerosols in the air in accordance with the information supplied by the manufacturer.

The product meets the class FFP2 requirements.

2. Sample withdrawal

The samples of respirator R-DP-R-FFP2-01 FFP2 NR for laboratory tests were supplied by the manufacturer on 10 November 2020 in the number of 60 pieces. The samples were registered in the Laboratory Register under numbers 8907 - 8966.

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 and with the applicable essential health and safety requirements	0
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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 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)

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

7.3 Visual inspection

Requirement: The visual inspection shall also include the marking and the information supplied by the manufacturer.

Evaluation: Samples have satisfied the requirement

7.4 Packaging

Requirement: 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.

Evaluation: Samples have satisfied the requirement

7.5 Material

Requirement: 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. After undergoing the simulated wearing treatment none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps. After the temperature conditioning or the simulated wearing treatment the particle filtering half mask shall not collapse. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.

Discovered: After test of temperature resistance particle filtering half masks show no visible changes. After the mechanical resistance test, respirator show no mechanical flaws. After simulated wearing treatment test respirator show no visible changes.

Evaluation: Samples have satisfied the requirement

7.6 Cleaning and disinfecting

Not applicable

7.7 Practical performance

Requirement: The particle filtering half mask shall undergo practical performance tests under realistic conditions.

Discovered: The respirator can be fastened with a buckle behind the head for better tightness. A respirator clamped behind the head can press on the nose. No other negative findings about the tested respirator were found.

Evaluation: Samples have satisfied the requirement

7.8 Finish of parts

Requirement: Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.

Evaluation: Samples have satisfied the requirement

7.9 Leakage

7.9.1 Total inward leakage

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:

Test subjects 4, 8 and 10 had a respirator head harness behind their ears. The other test subjects had a respirator head harness connected by a buckle behind their head.

test subject	sample	condition	exercises					mean	
			a)	b)	c)	d)	e)		
1	JT	8931	TC	3,532	3,417	7,215	9,678	7,921	6,353
2	MDo	8932	TC	7,346	4,744	4,354	7,995	8,485	6,585
3	JBo	8933	TC	1,230	1,769	2,213	2,988	2,126	2,065
4	JS	8934	TC	3,817	5,696	4,863	6,874	5,983	5,446
5	MSk	8935	TC	7,250	4,144	4,691	5,261	3,977	5,065
6	NKu	8936	AR	1,262	2,880	5,259	9,880	6,536	5,164
7	JFo	8937	AR	4,823	5,936	5,438	9,884	6,697	6,555
8	LZ	8938	AR	0,660	1,353	3,697	3,418	2,681	2,362
9	PM	8939	AR	6,534	2,560	5,290	2,115	6,341	4,568
10	JP	8940	AR	3,444	4,979	6,368	8,952	4,526	5,654
mean				3,990	3,748	4,939	6,705	5,527	4,982

Exercises: a) walk only

b) head side to side

c) head up and down

d) reciting an alphabet

e) walk only

AR As received

TC Temperature conditioned

Facial dimensions of test subjects

test subject	face length mm	face width mm	face depth mm	mouth width mm	
1	JT	121	126	138	54
2	MDo	110	140	104	58
3	JBo	104	145	104	60
4	JS	118	145	135	59
5	MSk	106	126	116	52
6	NKu	113	132	130	61
7	JFo	114	122	123	56
8	LZ	109	132	131	50
9	PM	113	129	145	55
10	JP	127	128	138	44

Evaluation: Samples have satisfied the requirement

7.9.2 Penetration of filter material

Requirement: The penetration of sodium chloride aerosol shall not exceed for class FFP2 the value of 6 %.

Discovered:

Initial penetration of sodium chloride aerosol

sample	condition	penetration %
8913	MS+TC	0,14
8914	MS+TC	0,15
8915	MS+TC	0,05
8919	AR	0,09
8920	AR	0,06
8921	AR	0,06
8927	SW	0,03
8926	SW	0,15
8925	SW	0,13

Notice: AR - As received
MS - Mechanical strength
TC - Temperature conditioned
SW - Simulated wearing treatment

The highest measured value of penetration of sodium chloride aerosol

sample	condition	penetration %	time of the highest measured value in minutes
8913	MS+TC	0,14	3
8914	MS+TC	0,15	3
8915	MS+TC	0,05	3

Requirement: The penetration of paraffin oil aerosol shall not exceed for class FFP2 the value of 6 %.

Discovered:

Initial penetration of paraffin oil aerosol

sample	condition	penetration %
8910	MS+TC	0,11
8911	MS+TC	0,21
8912	MS+TC	0,093
8916	AR	0,07
8917	AR	0,09
8918	AR	0,12
8928	SW	0,1
8929	SW	0,078
8930	SW	0,051

Penetration of paraffin oil aerosol after exposition of 120 mg oil

sample	condition	penetration %
8910	MS+TC	0,33
8911	MS+TC	0,67
8912	MS+TC	0,26

Evaluation: Samples have satisfied the requirement

7.10 Compatibility with skin

Requirement: 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.

Discovered: The manufacturer submits documents in the documentation on the health safety of the materials used.

Evaluation: Samples have satisfied the requirement

7.11 Flammability

Requirement: 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 for more than 5 s after removal from the flame.

Discovered: None materials of half mask burn, glow or drip. After passing through the flame, no part of half mask continues to burn, only the top layer partially melts.

Evaluation: Samples have satisfied the requirement

7.12 Carbon dioxide content of the inhalation air

Requirement: The carbon dioxide content of the inhalation air shall not exceed an average of 1 % (by volume).

Discovered:

sample	condition	CO ₂ concentration % vol.
8922	AR	0,33
8923	AR	0,46
8924	AR	0,41
mean		0,40

Evaluation: Samples have satisfied the requirement

7.13 Head harness

Requirement: The head harness shall be designed so that the particle filtering half mask can be donned and removed easily. 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 be capable of maintaining total inward leakage requirements for the device.

Discovered: The respirator has the ear loops, but it is possible to fasten it with a buckle behind the head to achieve better tightness.

Evaluation: Samples have satisfied the requirement

7.14 Field of vision

Requirement: The field of vision is acceptable if determined so in practical performance tests.

Discovered:

Evaluation: Samples have satisfied the requirement

7.15 Exhalation valve(s)

Not applicable

7.16 Breathing resistance

Requirement: The inhalation resistance for class FFP2 shall not exceed 70 Pa at flow of 30 l/min and 240 Pa at flow of 95 l/min.

Inhalation resistance

Discovered:

sample	condition	resistance Pa	
		at 30 l/min	at 95 l/min
8907	TC	35	126
8908	TC	38	122
8909	TC	37	124
8922	AR	39	133
8923	AR	40	137
8924	AR	38	135
8924	SW	47	165
8925	SW	43	167
8926	SW	47	162

Requirement: The exhalation resistance for class FFP2 shall not exceed 300 Pa at flow of 160 l/min.

Discovered:

sample	condition	position				
		ahead	down	up	left	right
		Pa	Pa	Pa	Pa	Pa
8907	TC	218	217	218	217	217
8908	TC	209	208	209	207	208
8909	TC	212	209	210	208	208
8922	AR	217	215	217	214	215
8923	AR	220	218	220	216	217
8924	AR	217	216	217	215	214
8924	SW	230	228	230	230	228
8925	SW	232	230	232	231	232
8926	SW	222	220	221	222	222

Evaluation: Samples have satisfied the requirement

7.17 Clogging

Not applicable

7.18 Demountable parts

Not applicable

V. Conformity assessment to the essential requirements

The conformity of the product with all relevant essential health and safety requirements mentioned in Regulation (EU) 2016/425 ANNEX II, has been assessed during EU type examination.

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 149:2001+A1:2009.

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-810/2020 dated 10. 11. 2020
3. Contract about EU-type examination no. 012/2021 dated 5. 2. 2021
4. Test report no. 036/2021 dated 5. 2. 2021
5. Test report no. 050/2021 dated 8. 2. 2021
6. Technical documentation, declaration of manufacturer
7. 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)