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-114/2020

Pages:	7	Copies:	3
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I. Source data

Name:	**Respirator face mask**
Type:	**R-DP-R-FFP3-01**
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-745/2020 dated: 1. 10. 2020
Contract:	102/2020 dated: 14. 12. 2020
Certified by:	Ing. L. Zavřel
Date of report issue:	16. 12. 2020

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

Respirator face mask R-DP-R-FFP3-01 FFP3 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 FFP3 requirements.

2. Sample withdrawal

The samples of respirator R-DP-R-FFP3-01 FFP3 NR for laboratory tests were supplied by the manufacturer on 15 and 21 September and 10 November 2020 in the number of 10, 50 and 19 pieces. The samples were registered in the Laboratory Register under numbers 7719 – 7728, 7874 - 7923 and 8888 - 8906.

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

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.
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 has to be fastened with a clip behind the head to achieve the highest possible level of protection. During practical tests no noticeable failures 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 5 % for class 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 2 % for class FFP3.
Discovered:

All test subjects had respirator connected by a clip behind their head.

test subject		sample	condition	exercises					mean
				a)	b)	c)	d)	e)	
1	JP	8899	TC	1,084	1,133	1,594	2,838	1,733	**1,676**
2	ETi	8889	TC	1,674	1,712	1,777	3,985	1,126	**2,055**
3	LZ	8890	TC	1,137	0,863	0,935	0,522	0,867	**0,865**
4	JFo	8891	TC	1,314	1,530	1,808	2,757	1,948	**1,871**
5	IHe	8898	TC	1,303	1,385	1,202	3,800	2,334	**2,005**
6	MDo	8893	AR	0,296	1,291	1,484	3,505	2,274	**1,770**
7	MSk	8894	AR	1,534	1,670	1,931	2,319	1,711	**1,833**
8	JT	8895	AR	1,803	2,166	2,492	3,209	1,545	**2,243**
9	PM	8896	AR	2,266	2,164	2,113	2,977	1,869	**2,278**
10	JBo	8897	AR	1,361	1,450	1,730	1,919	1,584	**1,609**
mean				1,377	1,536	1,707	2,783	1,699	**1,820**

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	JP	127	128	138	44
2	ETi	118	116	129	54
3	LZ	109	132	131	50
4	JFo	114	122	123	56
5	IHe	114	131	126	52
6	MDo	110	140	104	58
7	MSk	106	126	116	52
8	JT	121	126	138	54
9	PM	113	129	145	55
10	JBo	104	145	104	60

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 FFP3 the value of 1 %.
Discovered:

Initial penetration of sodium chloride aerosol

sample	condition	penetration %
7892	MS+TC	0,01
7893	MS+TC	0,01
7894	MS+TC	0,02
7880	SW	0,05
7881	SW	0,12
7882	SW	0,24
7877	AR	0,02
7878	AR	0,31
7879	AR	0,02

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
7892	MS+TC	0,01	3
7893	MS+TC	0,01	3
7894	MS+TC	0,02	3

Requirement: The penetration of paraffin oil aerosol shall not exceed for class FFP3 the value of 1 %.
Discovered:
Initial penetration of paraffin oil aerosol

sample	condition	penetration %
7725	AR	0,0011
7726	AR	0,0016
7727	AR	0,017
7889	MS+TC	0,0022
7890	MS+TC	0,025
7891	MS+TC	0,0046
7883	SW	0,44
7884	SW	0,012
7885	SW	0,01

Penetration of paraffin oil aerosol after exposition of 120 mg oil

sample	condition	penetration %
7889	MS+TC	0,0049
7890	MS+TC	0,027
7891	MS+TC	0,0094

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 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.
7874	AR	0,41
7875	AR	0,45
7876	AR	0,37
mean		0,41

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 necessary to fasten it with a clip behind the head to achieve the highest possible level of protection
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 FFP3 shall not exceed 100 Pa at flow of 30 l/min and 300 Pa at flow of 95 l/min.

Inhalation resistance
Discovered:

sample	condition	resistance Pa	
		at 30 l/min	at 95 l/min
7880	SW	57	199
7881	SW	54	184
7882	SW	55	189
7886	TC	50	178
7887	TC	52	167
7888	TC	48	178
7719	AR	51	162
7720	AR	51	163
7721	AR	50	162

Requirement: The exhalation resistance for class FFP3 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
7880	SW	292	296	297	299	299
7881	SW	291	292	291	292	291
7882	SW	287	285	286	282	283
7886	TC	259	254	255	261	260
7887	TC	272	272	270	269	270
7888	TC	285	285	284	283	284
7719	AR	271	269	270	270	271
7720	AR	273	270	272	271	272
7721	AR	270	268	270	269	269

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-745/2020 dated 1. 10. 2020
3. Contract about EU-type examination no. 102/2020 dated 14. 12. 2020
4. Test report no. 656/2020 dated 16. 9. 2020
5. Test report no. 667/2020 dated 2. 10. 2020
6. Test report no. 689/2020 dated 10. 12. 2020
7. Test report no. 765/2020 dated 11. 12. 2020
8. Technical documentation, declaration of manufacturer
9. 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)