

FINAL REPORT ON CERTIFICATION *

1024/ZZ-035/2021

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I. Source data

Name: **Full face mask**

Type: **CM-6** and derived versions **CM-6M, CM-6S, CM-6MS** with 5 and 6 point head harness system
CM-6-MED (Medical) with 5 and 6 point head harness system
CM-6P, CM-6MP with 5 and 6 point head harness system

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

Manufacturer: GUMÁRNÝ ZUBŘÍ, akciová společnost, Hamerská 9, 756 54 Zubří, Czech Republic

Application: S-901/2020 dated: 14. 12. 2020

Contract: 027/2021 dated: 26. 3. 2021

Certified by: Ing. L. Zavřel

Date of report issue: 7. 5. 2021



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. archive of laboratory
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. Product description

Full face mask **CM-6** and derived versions **CM-6S**, **CM-6P**, **CM-6MED** with 5 and 6 point head harness system and derived versions **CM-6M**, **CM-6MS**, **CM-6MP** with equipment liquids intake with 5 and 6 point head harness system in combination with suitable filter provides the protection of respiratory system, face and eyes of a user against harmful pollutants in the air, depending on the type of the filter which is used and in accordance with the information supplied by the manufacturer.

The full face mask meets the class 3 (CL3) requirements.

The full face masks CM-6S and CM-6MS with equipment liquids intake are the same as the masks CM-6 and CM-6M with equipment liquids intake, the difference is only in the material used in the inner mask.

The inner mask of CM-6S and CM-6MS is made of silicone (MF 71 791/50L R 9005).

The full face mask CM-6-MED has material of facepiece and an inner masks from natural rubber in white. Plastic parts are made of POM (polyoxymethylene) in blue.

The CM-6P and CM-6MP full face masks have an inner mask made of TPE (thermoplastic elastomer) material.

Certificate no. 235/E-005/2016 (NB 1024) has already been issued for the full face mask CM-6 and derived versions CM-6S, CM-6M, CM-6MS. The executor will use the Final report no. 235/ZZ-005/2016 together with the results stated therein. The product is regularly inspected, the results are given in annual control reports no. 1024/ZK-010/2019, no. 235/ZK-009/2018 and no. 235/ZK-007/2017.

2. Sample withdrawal

Samples of the full face mask CM-6-MED and CM-6P for laboratory tests were supplied by the manufacturer in the number of 1 piece on 25 February 2021 and 1 piece on 15 March 2021. The samples were registered in the Laboratory Register under numbers 1171 (CM 6 MED) and 1420 (CM 6P).

See Final report no. 235/ZZ-005/2016

The samples of mask for laboratory tests were taken on 2. 6. 2015 in the number of 4 pieces and were registered in the Laboratory Register under numbers 331 - 334.

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	0
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	0
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 136:1998, EN 136:1998/AC:2003 Respiratory protective devices. Full face masks. Requirements, testing, marking (idt. ČSN EN 136:1998, ČSN EN 136 Oprava 1:2000)

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

7.3 Visual inspection

Requirement: The visual inspection shall include that of the marking and of any information to be supplied by the manufacturer.

Evaluation: Samples have satisfied the requirement

7.4 Materials

Requirement: For class 2 and class 3 full face masks exposed parts i.e. those which may be subjected to impact during use of the apparatus shall not be made of aluminium, magnesium, titanium or alloys containing such proportions of these metals as will, on impact, give rise to frictional sparks capable of igniting flammable gas mixtures.

Evaluation: Samples have satisfied the requirement

7.5 Resistance to temperature

Requirement: Before and after this test the full face mask shall meet the requirement of 7.16. Following the conditioning in accordance with 8.2 and after being allowed to return to ambient temperature the full face mask shall show no appreciable deformation and any incorporated threaded connector to EN 148-1, EN 148-2 or EN 148-3 shall be gauged and shall comply with the appropriate standard.

Discovered: see Final report no. 235/ZZ-005/2016

After the conditioning the full face mask shows no appreciable deformation and meets the requirement for the leaktightness.

Evaluation: Samples have satisfied the requirement

7.6 Flammability

7.6.1 General

Requirement: Before and after these tests the full face mask shall meet the requirement of 7.16.

7.6.3 Class 2 and class 3 full face masks

Requirement: Parts of the full face mask that might be exposed to a flame during use shall not burn or continue to burn for more than 5 s after removal from the flame.

Discovered: see Final report no. 235/ZZ-005/2016

The facepiece, the visor and the other material of mask do not burn after the removal from the flame.

There is no deformation after the visual inspection of samples.

the leaktightness after test of flammability

condition	change of pressure (Pa)
after test of flammability	less than 100

Evaluation: Samples have satisfied the requirement

7.7 Resistance to thermal radiation

Requirement: Class 3 full face masks shall be resistant to thermal radiation. Before and after the thermal radiation test the full face mask shall meet the requirement of 7.16.

Discovered:

CM-6-MED, Sample No. 1171

after exposure 4 min. the view is not disturbed, after approx. 7 min. the lens frame is partially melted and bubbles begin to form in the lens. After 8 minutes, the test was terminated. The leaktightness requirement after thermal radiation test is met

sample	condition	change of pressure (Pa)
1171	after 8 min of thermal radiation test	less than 100

see Final report no. 235/ZZ-005/2016

After 20 min exposition the visibility is not impaired

After 4,5 min exposition the visibility is not impaired

The leaktightness requirement after thermal radiation test is met

condition	change of pressure (Pa)
after 20 min of thermal radiation test	less than 100
after 4 min of thermal radiation test	less than 100

Evaluation: Samples have satisfied the requirement

7.8 Cleaning and disinfecting

Requirement: The materials used shall withstand the cleaning and disinfecting agents and procedures as recommended by the manufacturer.

Discovered: see Final report no. 235/ZZ-005/2016

The mask material is resistant to common cleaning and disinfecting agents.

Evaluation: Samples have satisfied the requirement

7.9 Finish of Parts

Requirement: The finish of any part of the full face mask likely to be in contact with the wearer shall be free from sharp edges and burrs.

Discovered: see Final report no. 235/ZZ-005/2016

There are no sharp edges on mask.

Evaluation: Samples have satisfied the requirement

7.10 Replaceable components

Requirement: Unless integral with the full face mask the following components (when fitted) shall be replaceable

Evaluation: Samples have satisfied the requirement

7.11 Head harness

7.11.1 Requirement: The head harness shall be designed so that the full face mask can be donned and removed easily.

7.11.2 Requirement: The head harness shall be adjustable or self-adjusting and shall hold the full face mask firmly and comfortably in position.

7.11.3.2 Requirement: For class 2 and class 3 full face masks each strap of the head harness shall withstand a pull of 150 N applied for 10 s in the direction of pulling when the full face mask is donned. Buckles and attachment lugs (if present) shall withstand the same pull.

7.11.4 Requirement: There shall be no permanent linear deformation of each strap of more than 5 % after having been tested at a pull of 50 N for 10 s.

Discovered: see Final report no. 235/ZZ-005/2016

The mask can be donned and removed easily. The head harness is adjustable. All parts of the head harness withstood a pull of 150 N applied for 10 s. There was no permanent deformation of each strap of more than 5 % after testing at a pull of 50 N for 10 s. The maximum deformation of the strap was 1,7 %.

Evaluation: Samples have satisfied the requirement

7.12 Connector

7.12.1 General

Requirement: The connection between the full face mask and the apparatus may be achieved by a permanent or special type of connection or by a threaded connection. 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. 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. Correct and reliable connection between facepiece and other parts of the equipment shall be assured.

7.12.3 Class 2 and class 3 full face masks

Requirement: Full face masks shall have only one threaded connector defined in EN 148-1, EN 148-2 or EN 148-3. If any other connector is used it shall not be possible to connect it to the threads defined in EN 148-1, EN 148-2 or EN 148-3.

7.12.4 Strength of connection

7.12.4.1 Requirement: Before and after this test the full face mask shall meet the requirement of 7.16.

7.12.4.3 Requirement: For class 2 and class 3 full face masks the connection between the faceblank and the connector shall be sufficiently robust to withstand axially a tensile force of 500 N.

Discovered: see Final report no. 235/ZZ-005/2016

The mask has one the threaded connector defined in EN 148-1, the second one is always sealed with the cover. The connection between the facepiece and the connector withstood a tensile force of 500 N.

Evaluation: Samples have satisfied the requirement

7.13 Speech diaphragm

7.13.1 Requirement: Where the facepiece includes a speech diaphragm the latter shall be protected against mechanical damage as assessed by visual inspection in accordance with 8.3.

The speech diaphragm shall withstand a differential pressure of 80 mbar (static pressure) with the positive pressure on the outside (ambient atmosphere).

7.13.2 Requirement: When a speech diaphragm assembly can be subjected to an external force it shall withstand axially a tensile force of 150 N applied for 10 s. The test shall be repeated nine times at 10 s intervals.

Discovered: see Final report no. 235/ZZ-005/2016

The speech diaphragm is protected against mechanical damage and has withstood a static pressure of 8 kPa.

Evaluation: Samples have satisfied the requirement

7.14 Eyepieces/visor

7.14.1 Requirement: Eyepieces/visor and anti-mist discs designed to serve as visors shall be attached in a reliable and gastight manner to the faceblank.

7.14.2 Requirement: Eyepieces and visors shall not distort vision as determined in practical performance tests.

7.14.3 Requirement: The manufacturer shall provide means to reduce misting of the eyepieces or visors so that vision is not interfered with when the apparatus is tested in the practical performance tests. Where

anti-fogging compounds are used as intended or specified by the manufacturer, they shall not be known to be likely to cause irritation or any other adverse effect to health.

7.14.4 Requirement: After the test for mechanical strength of the eyepiece(s) or visor the facepiece shall not be damaged in any way that may make it ineffective or cause injury to the wearer. The effectiveness shall be tested by comparing the tightness of the full face mask before and after the test. The full face mask shall meet the requirements of 7.16 both before and after the test for mechanical strength of the eyepiece or visor.

Discovered: see Final report no. 235/ZZ-005/2016

The visor is attached in a gastight manner to the facepiece and it do not distort the vision. The visor satisfied the test for mechanical strength.

Evaluation: Samples have satisfied the requirement

7.15 Inhalation valves and exhalation valves

7.15.1 General

Requirement: Valve assemblies shall be such that they can be readily maintained and if intended by the manufacturer correctly replaced. It shall not be possible to fit an exhalation valve assembly into the inhalation circuit or an inhalation valve assembly into the exhalation circuit. Inhalation and exhalation valve assemblies, sub-assemblies and piece parts that are designed by the manufacturer to be identical, are acceptable. Differently designed inhalation and exhalation valve assemblies, sub-assemblies and piece parts are acceptable if a precise and comprehensible description is given in the information supplied by the manufacturer. To enable correct assembling, the parts shall be unambiguously described or marked. Means to check the correct assembly shall be described.

7.15.2 Inhalation valves

7.15.2.1 Requirement: Inhalation valves shall function correctly in all orientations and meet the requirements of 7.19.

7.15.2.2 Requirement: A full face mask with a threaded connection to EN 148-2 shall not have an inhalation valve. If a threaded connection to EN 148-1 is used, an inhalation valve shall be incorporated in the full face mask. If a full face mask has to be used with filters it shall be provided with an inhalation valve, if there is no valve in the filter.

7.15.3 Exhalation valves

7.15.3.2 Requirement: Exhalation valves shall function correctly in all orientations and meet the requirements of 7.19.

7.15.3.3 Requirement: A full face mask fitted with a threaded connection to EN 148-1 or EN 148-3 and a full face mask class 1 shall have at least one exhalation valve or other appropriate means to allow the escape of exhaled air and/or excess air.

7.15.3.4 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 be necessary to comply with 7.20.

7.15.3.5 Requirement: Exhalation valves shall continue to operate correctly and meet the requirements of 7.19 after (a) a continuous exhalation flow of 300 l/min and (b) a negative pressure (static) in the facepiece of 80 mbar (30 s for each test).

7.15.4 Tensile force

7.15.4.2 Class 2 and class 3 full face masks

Requirement: Before and after the test the full face mask shall meet the requirement of 7.16. When the exhalation valve housing is attached to the faceblank it shall withstand axially a tensile force of 150 N applied for 10 s. The test shall be repeated 9 times at 10 s intervals.

Discovered: see Final report no. 235/ZZ-005/2016

Inhalation and exhalation valves are functional in all orientations. The exhalation valve operates correctly even after a continuous exhalation flow of 300 l/min and after a negative pressure in the facepiece of 8 kPa applied for 30 s. The exhalation valve housing withstood a tensile force of 150 N applied for 10 s, the mask meets the requirement for the leaktightness after this test.

Evaluation: Samples have satisfied the requirement

7.16 Leaktightness

Requirement: The leakage of the full face mask shall not exceed that indicated by a change of pressure of 100 Pa in 1 min, when tested with 1 kPa negative pressure.

Discovered:

The change of pressure did not exceed 100 Pa in 1 min.

sample	condition	change of pressure (Pa)
1171	as received	less than 100
1171	after 8 min of thermal radiation test	less than 100

see Final report no. 235/ZZ-005/2016 - mask CM-6

condition	change of pressure (Pa)
as received	less than 100
after temperature conditioning	less than 100
after test of flammability	less than 100
after test of thermal radiation	less than 100
after tensile force test of valve housing	less than 100
after tensile force test of connection	less than 100
after test for mechanical strength of visor	less than 100

see Final report no. 235/ZZ-005/2016 - mask CM-6M

condition	change of pressure (Pa)
as received	less than 100
after temperature conditioning	less than 100
after test of flammability	less than 100
after test of thermal radiation	less than 100
after tensile force test of valve housing	less than 100

Evaluation: Samples have satisfied the requirement

7.17 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 have any other adverse effect to health

Evaluation: Samples have satisfied the requirement

7.18 Carbon dioxide content of the inhalation air

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

Discovered: see Final report no. 235/ZZ-005/2016

sample	conditioning	CO ₂ concentration (vol. %)
332	AR	0,541

mask	CO ₂ concentration (vol. %)
CM-6	0,88
CM-6M	0,56
CM-6M	0,25
CM-6S	0,94
CM-6MS	0,96

Evaluation: Samples have satisfied the requirement

7.19 Breathing resistance

7.19.2 Requirement: The inhalation resistance shall not exceed 50 Pa at continuous flow of 30 l/min, 150 Pa at continuous flow of 95 l/min and 250 Pa at continuous flow of 160l/min.

The exhalation resistance shall not exceed 300 Pa at continuous flow of 160l/min.

Discovered: Mask CM-6P

Inhalation resistance

condition	AR	resistance (Pa)				
		position				
sample	flow rate (l/min)	ahead	down	up	left	right
1420	30	19	18	19	20	19
	95	95	96	98	95	95
	160	218	217	221	220	218

Exhalation resistance

flow rate 160 l/min		resistance (Pa)				
		position				
sample	condition	ahead	down	up	left	right
1420	AR	232	233	235	234	235

Notice: AR - as received

Inhalation resistance

condition	AR	resistance (Pa)				
		position				
sample	flow rate (l/min)	ahead	down	up	left	right
909	30	14	14	14	15	14
	95	91	92	91	90	91
	160	222	224	223	222	222
910	30	16	16	17	17	16
	95	78	81	80	78	79
	160	189	191	185	190	189
911	30	17	17	16	17	17
	95	90	89	89	90	90
	160	214	214	215	215	214

Note: AR - as received

Exhalation resistance

flow rate 160 l/min		resistance (Pa)				
		position				
sample	condition	ahead	down	up	left	right
909	AR	251	253	255	250	251
910	AR	229	233	234	230	231
911	AR	252	251	252	251	251

Evaluation: Samples have satisfied the requirement

7.20 Inward leakage

Requirement: A full face mask shall fit against the contours of the face. The inward leakage of the test agent shall not exceed an average value of 0,05 % of the inhaled air for any of the ten test subjects in any of the test exercises.

Discovered: see Final report No. 235/ZZ-005/2016

test subject	condition	exercises					mean	
		a)	b)	c)	d)	e)		
1	MB	AR	0,018	0,026	0,014	0,029	0,018	0,021
2	EP	AR	0,010	0,010	0,008	0,022	0,008	0,012
3	KF	AR	0,004	0,004	0,008	0,014	0,004	0,007
4	JB1	AR	0,010	0,010	0,012	0,022	0,004	0,011
5	NZ	AR	0,021	0,024	0,016	0,027	0,016	0,021
6	MD1	TC	0,016	0,016	0,015	0,022	0,015	0,017
7	MD2	TC	0,028	0,020	0,019	0,029	0,015	0,022
8	BB	TC	0,022	0,017	0,023	0,023	0,017	0,020
9	JB2	TC	0,004	0,010	0,010	0,015	0,004	0,009
10	LZ	TC	0,004	0,008	0,010	0,016	0,010	0,010
mean			0,014	0,015	0,014	0,022	0,011	0,015

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

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	MB	113	118	112	51
2	EP	118	126	138	54
3	KF	110	112	120	45
4	JB1	114	124	130	56
5	NZ	108	112	119	46
6	MD1	110	140	108	55
7	MD2	111	129	135	59
8	BB	118	132	114	54
9	JB2	104	145	104	60
10	LZ	109	132	131	50

Evaluation: Samples have satisfied the requirement

7.21 Field of vision

Requirement: A full face mask equipped with a single visor shall be designed so that the effective field of vision shall be not less than 70 %, related to the natural field of vision, and the overlapped field of vision, related to the natural overlapped field of vision, shall be not less than 80 %.

Discovered: see Final report No. 235/ZZ-005/2016

effective field of vision	77,6 % natural field of vision
overlapped field of vision	83,8 % natural overlapped field of vision

Evaluation: Samples have satisfied the requirement

7.22 Practical performance

Requirement: The entire device must be subjected to practical performance tests under realistic conditions.

Discovered: see Final report No. 235/ZZ-005/2016

No deficiencies were found during the practical tests.

Evaluation: Samples have satisfied the requirement

V. Conformity assessment to the basic 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 136:1998,
EN 136:1998/AC:2003.

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 about EU type examination no. S-901/2020 dated 14. 12. 2020
3. Contract about EU type examination no. 027/2021 dated 26. 3. 2021
4. Test report no. 126/2021 dated 27. 3. 2021
5. Test report no. 147/2021 dated 16. 4. 2021
6. Final Report on certification no. 235/ZZ-005/2016 dated 29. 2. 2016
7. EC type examination certificate no. 235/E-005/2016 dated 29. 2. 2016
8. Declarations of manufacturer, technical documentation
9. EN 136:1998, EN 136:1998/AC:2003 Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking (idt. ČSN EN 136:1998, ČSN EN 136 Oprava 1:2000)