



INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a. s.

třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Testing Laboratory

Testing laboratory * Calibration laboratory * Product certification body * Quality management systems certification body
Inspection body * Authorized body * Notified body

Number of pages: 7

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TEST REPORT

ref. No. 462203971-01

Client: WCA Holding a.s.
VAT No.: CZ07302363

Address: Vinohradská 2577/178,
130 00 Praha Vinohrady,
Czech Republic

Sample: Medical face mask, see page 2

Sample received on: June 24, 2020

Report elaborated by: Radek Matějka

Place and date of issue: Zlín, June 26, 2020

Ing. Jiří Samsonek, Ph.D.
Head of Testing Laboratory

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Description and identification of samples:

Table No. I - Sample description and identification

ITC's identification number	Sample identification by client	Description of submitted sample
462203971/01	Product: Medicak face mask, Producer: medic armor s.r.o.; IČO: 06448216 Záměstní 1155/27, Slezská Ostrava; 710 00 Ostrava	Medical face mask, white/blue, see Fig. 1



Fig. No.1 – Picture of samples no. 462203971/01

Sampling method used:

The test sample was collected and supplied to the laboratory by the client. The laboratory is not responsible for this way of sampling

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Work requested:

Determination of selected physical-mechanical properties – Medical face mask testing

Testing method used:

1. Testing the properties of medical mask – Material, construction and design acc. Internal test specification ITC No. P-20-25 (requirement ČSN EN 14638+AC, 5.1)
2. Testing the properties of medical mask – determination of bacterial filtration efficiency acc. ČSN EN 14638+AC, 5.2.2 – sub-delivery
3. Testing the properties of medical mask – determination of breathability acc. ČSN EN 14638+AC, 5.2.3
4. Testing the properties of medical mask – determination of splash resistance acc. ISO 22609 (requirement ČSN EN 14638+AC, 5.2.4)
5. Testing the properties of medical mask – determination of microbial cleanliness acc. ČSN EN 14638+AC, 5.2.5 – sub-delivery
6. Testing the properties of medical mask – determination of biocompatibility acc. SOP 1/3 and SOP 2/3 (Requirement ČSN EN 14638+AC, 5.2.6) – sub-delivery

Test conditions:

1. Samples conditioning (23±5)°C; (85±5)% R.h.; min 4 h
Face sizes S/M, L, XL
No. of tested specimens 3
2. No. of tested specimens 3 (deviation form the standard)
Tested area min 49 cm²
Samples conditioning (23±5)°C; (85±5)% R.h.; min 4 h
Side of the mask in contact with the bacterial challenge Inner side
Challenge bacterial strain used Staphylococcus aureus ATCC6538
Bacterial challenge per test 1700-3000 FCU
Total test time 1 min. delivering challenge + 1 min. without challenge (air flow continuing)
Flow rate 28,3 min
Positive control Test performed with no filter material in air stream
Negative control Test performed without challenge
Deviation from the standard Test result based on 3 instead of 5 samples
3. No. of tested specimens 5
Samples conditioning (23±5)°C; (85±5)% R.h.; min 4 h
Air flow rate 8 l/min
Flow direction outer side to inner side
Diameter of tested area 25 mm (4,9 cm²)
No of measurements for spec. 5
4. Samples conditioning (23±5)°C; (85±5)% R.h.; min 4 h
No. of tested specimens 32
Tested canula used dia. 0,84mm / 12,7mm

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Testing medium	synthetic blood (acc. ISO 22609 – Annex B)
Surface tension	40 – 44 * 10 ⁻³ N/m
Volume of the delivered blood	2 ml
Distance (canula – mask)	(300±10) mm
Evaluation time	10 s (after the test)
5. No. of tested specimens	5
Extraction liquid	Peptone 1g/l, NaCl 5g/l, Tween20 2g/l
Extraction volume	300 ml
Extraction time	5 min
Counting technique	Membrane filtration
Filtration volume	100 ml
Culture media	TSA (Tryptic soy agar) SDA (Sabouraud Dextrose Agar with chloramphenicol)
Incubation condition	3 days at 30°C (TSA) 7 days at 20-25 (SDA)
Deviation from the standard	Performed on 3 specimens instead of 5 specimens
6. Acc. SOP 1/3 (ISO 10993-5: part 5 / 1, 2, 3, 4, 5, 6, 7, 8.1, 8.2, 8.3, 8.5, 9, 10, Annex A)	
No of tests	2
Cell line	mouse Fibroblasts - Balb / c 3T3-L1 line
Culture medium	D-MEM with containing antibiotics + 10% inactivated calf serum
Other condition	Acc. report no. 3/20/100
Acc. SOP 2/3 (ISO 10993-10: part 10 / 1, 2, 3, 4, 5, 6.2, 6.3, 6.4, 6.5, 7.5, Annex A, B1, B2, C, E, F)	
No. of tested specimens	30
Exposition time	max 4h
Classification time	0-72 h
Others condition	acc. report No. 3/20/100

The laboratory is not responsible for information received from customer, which could have influence on the validity of the results. Further information required by standards and not given in this Test Report are available at a request at the Laboratory.

Testing laboratory:

Test No. 1,2 a 4	Workplace No. 2, třída Tomáše Bati 5264, Svit premises, building No. 113, 760 01 Zlín, Czech Republic.
Test No. 3 and 5	Sub-delivery HYGCEM
Test No. 6	Sub-delivery SZU

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Test result:

The test results are given in the following table:

Table No. II – Results of visual check – sample 462203971/01

Description of construction¹⁾	Rectangular shape Dimensions (175x95)mm Folded: yes Nose bridge: yes
Method of fixing the mask on the face¹⁾	2 elastic bands on the shorter sides of rectangle
Mask structure¹⁾	3 layers; fixed on edges acc. Fig.No.2

¹⁾ acc. P-20-25


Fig. No.2 – Picture of samples no. 462203971/01

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**Table No. III – Results of visual check – sample 462203971/01**

Testing person with face size ¹⁾ :	Visual and function evaluation after 5 application
M,S	Mask without defect
L	Mask without defect
XL	Mask without defect

1) acc. P-20-25

Table No. IV – Results for practical application – sample 462203971/01

Testing person with face size ¹⁾ :	Evaluation of the test
M,S	Attaching the face mask: The mask holds firmly on head and face. Mask does not deform unnaturally under various movements of head, does not fall down to chin or does not move towards eyes. Mask tightness on face: The mask copies shape of face. When inhaling and exhaling, most of air passes through mask
L	Attaching the face mask: The mask holds firmly on head and face. Mask does not deform unnaturally under various movements of head, does not fall down to chin or does not move towards eyes. Mask tightness on face: The mask copies shape of face. When inhaling and exhaling, most of air passes through mask
XL	Attaching the face mask: The mask holds firmly on head and face. Mask does not deform unnaturally under various movements of head, does not fall down to chin or does not move towards eyes. Mask tightness on face: The mask copies shape of face. When inhaling and exhaling, most of air passes through mask

1) acc. P-20-25

Table No. V – Results for bacterial efficiency test – sample 462203971/01

Specimen No.	Unit	Test result
1	%	In progress
2		In progress
3		In progress

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**Table No. VI – Result for breathability – sample 462203971-01**

Characteristics measured	Unit	Test result	Uncertainty ¹⁾
Differential pressure	Pa/cm ²	In progress	

¹⁾ expanded uncertainty for coverage factor $k = 2$, which for a normal distribution corresponds to a coverage probability of approximately 95%

Table No. VII – Result for splash resistance test - sample 462203971-01

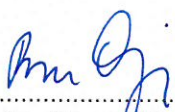
Characteristics measured	Test result
Splash resistance	32 test specimens - pass

Table No. VIII – Result for microbial cleanliness – sample 462203971-01

Specimen No.	Mask weight (g)	CFU / mask		Microbial cleanliness	
		Aerobic microbial count (bacteria)	Fungi count (SDA)	Σ CFU / mask	Σ CFU / g
1	In progress	In progress	In progress	In progress	In progress
2	In progress	In progress	In progress	In progress	In progress
3	In progress	In progress	In progress	In progress	In progress

Table No. IX – Result for biocompatibility test – sample 462203971-01

Characteristics measured	Test result
Toxicity of the extract	In progress
Irritation to human skin	In progress


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M.Sc. Roman Dlabaja, Ph.D.
Head of Laboratory of Physics

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