



INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a. s.

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

Testing Laboratory No. 1004

accredited by ČIA according to ČSN EN ISO/IEC 17025:2018



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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ACCREDITED LABORATORY TEST REPORT ref. No. 462204056-02

Client:

Address:

Sample: Medical face mask, see page 2

Sample received on: August 28, 2020

Report elaborated by: Radek Matějka

Place and date of issue: Zlín, October 01, 2020



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Ing. Jiří Samsonek, Ph.D.
Head of Accredited 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
462204056-01	Medical face mask WORKSHOP BFE98	Medical face mask, white/blue, see Fig. 1

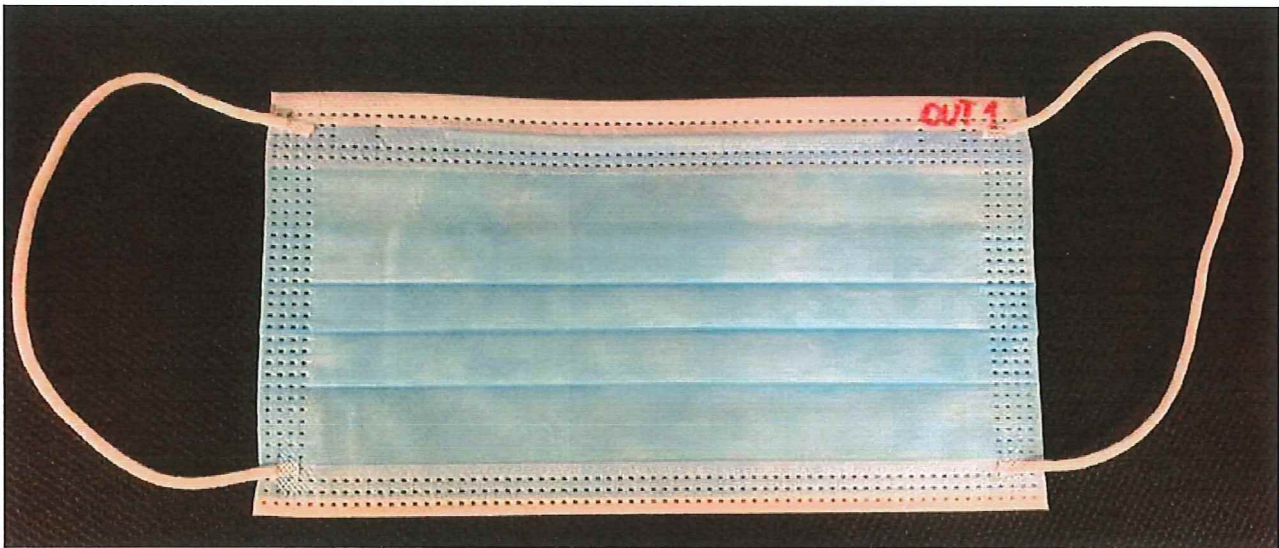


Fig. No.1 – Picture of samples no. 462204056/01

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

Work requested:

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

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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 14683+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 14683+AC, 5.2.3
4. Testing the properties of medical mask – determination of splash resistance acc. ISO 22609 (requirement ČSN EN 14683+AC, 5.2.4)
5. Testing the properties of medical mask – determination of microbial cleanliness acc. ČSN EN 14683+AC, 5.2.5 – 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 5
Tested area 50 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
CFU of test suspension: 5.5 x 10⁵/ml
Incubation 48h / (36±1)°C
Flow rate 28,3 min
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
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 time 5 min
Others test conditions acc. to report No. B 25575

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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 HYGCEN (report no.B25575)

Test result:

The test results are given in the following table:

Table No. II – Results of visual check – sample 462204056/01

Description of construction¹⁾	Rectangular shape Dimensions (172x95)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. 462204056/01

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Table No. III – Results of visual check – sample 462204056/01

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 462204056/01

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 462204056/01

Specimen No.	Unit	Test result
1	%	99,95
2		100
3		100
4		100
5		99,95
Mean Value		99,98

Table No. VI – Result for breathability – sample 462204056/01

Characteristics measured	Unit	Test result	Uncertainty ¹⁾
Differential pressure	Pa/cm ²	35,90	0,99

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 462204056/01

Characteristics measured	Test result
Splash resistance	30 test specimens – pass 2 test specimens - fail

Table No. VIII – Result for microbial cleanliness – sample 462204056/01

Characteristics measured	Unit	Test result
Cleanliness	cfu/g	15,78

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Comment on the results of the tests - /beyond the scope of accreditation:

The tested sample 462204056-01 fulfils the requirements of EN 14683:2019+AC:2019, for type IIR masks.

Table No. IX – Summarization of the result – sample 462204056/01

Characteristics measured	Unit	Test result	Value required ¹⁾ (For type IIR)	Evaluation
Bacterial efficiency	%	99,98	≥ 98	Pass
Differential pressure	Pa/cm ²	35,90	< 60	Pass
Splash resistance	kPa	16 30	≥ 16,0 ≥ 29 ²⁾	Pass
Cleanliness	Cfu/g	15,78	≤ 30	Pass

¹⁾ Requirements of EN 14683:2019+AC:2019, for type II masks

²⁾ The No. of 32 tested mask has been determined based on single sampling plan providing an AQL of 4% (acceptable quality limit) If 29 mask or more over 32 obtain a "Pass" result the 4% AQL is reached (requirement acc ISO 22609)

Evaluation and comment on the results of the tests carried out by:

Ing. Radek Matějka

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

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