



**CENTRAL INSTITUTE FOR LABOUR PROTECTION
- NATIONAL RESEARCH INSTITUTE**
Czerniakowska 16 Street, 00-701 Warsaw, POLAND

Department of Chemical, Aerosol and Biological Hazards –
Laboratory of Biohazards

TEST REPORT

Contract to perform testing No.: **781/PZ-TSB-COV/2020/NC**

SUBJECT OF THE CONTRACT: Testing of medical face masks for compliance with EN 14683:2019+AC with regard to filtration efficiency (BFE), microbiological cleanliness and breathability

ORDERING PARTY: BROTHERS WŁADYSŁAW BOCHNIARZ
Siedlce 141
33-322 Korzenna

Date of start
15.06.2020

Date of end
29.06.2020

The test report consists of 5 (five) pages.

	Scientific title/degree, given name and surname
Main performer	Rafał L. Górny, Ph.D., Prof. Tit.
Performers	Agata Stobnicka-Kupiec, Ph.D. Małgorzata Gołofit-Szymczak, Ph.D. Anna Ławniczek-Wałczyk, Ph.D Marcin Cyprowski, Ph.D Agnieszka Brochocka, BEng, PhD, DSc Krzysztof Makowski, MSc

KIEROWNIK ZAKŁADU
Zagrożeń Chemicznych, Pyłowych i Biologicznych

dr Małgorzata Pośniak

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AIM OF THE TESTS

The aim of the tests was to assess the bacterial filtration efficiency (BFE), microbiological cleanliness (bioburden) and breathability (differential pressure) of one batch of medical face masks supplied by BROTHERS WŁADYSŁAW BOCHNIARZ, Siedlce 141, 33-322 Korzenna, Poland.

TESTED MATERIALS

The tested materials consisted of 15 medical face masks made of non-woven fabric measuring 17.4×9.4 cm, in blue colour with bands.

METHODOLOGY

The tests were carried out in accordance with the requirements of European Standard EN 14683:2019+AC regarding:

- filtration efficiency of *Staphylococcus aureus* strain ATCC 6538 – according to Annex B,
- microbiological cleanliness (bioburden) – according to Annex D,
- breathability (differential pressure) – according to Annex C.

TEST RESULTS

Bacterial filtration efficiency test (BFE)

Table 1 shows the total number of bacteria that permeate the mask together with the calculated bacterial filtration efficiency for the medical mask tested in accordance with EN 14683:2019+AC.

Table 1. The results of bacterial filtration efficiency tests for evaluated medical masks.

Tested sample	Total bacterial count (cfu ^{*)}	Bacterial filtration efficiency (%)	Requirements of EN 14683:2019+AC
Negative control (mean of two negative control runs)	0	-	Bacterial filtration efficiency for particular types of medical masks should be: Typ I ≥95 % Typ II ≥98 % Typ IIR ≥98 %
Positive control (mean of two positive control runs)	4763	-	
Mask no. 1	7	99,9	
Mask no. 2	14	99,7	
Mask no. 3	7	99,9	
Mask no. 4	14	99,7	
Mask no. 5	14	99,7	

^{*)} cfu – colony-forming units

The bacterial filtration efficiency for the tested medical masks ranged from 99,7% to 99,9%. The average bacterial filtration efficiency for the tested masks was 99,8%.

Microbiological cleanliness (bioburden) test

Table 2 shows the results of bioburden test for medical masks.

Table 2. The results of the total bioburden test for evaluated medical masks.

Tested sample	Mass (g)	Total number of bacteria on the filter (cfu [*])	Total number of fungi on the filter (cfu)	Total number of micro-organisms (cfu/mask)	Total number of micro-organisms (cfu/g)	Requirements of EN 4683:2019+AC
Mask no. 6	3.2	24	0	72	22.5	Total bioburden for particular types of medical masks should be: Typ I, Typ II and Typ IIR ≤30 cfu/g
Mask no. 7	3.1	65	1	198	63.9	
Mask no. 8	3,2	30	0	90	28.1	
Mask no. 9	3.2	10	0	30	9.4	
Mask no. 10	3.2	19	1	60	18.8	

^{*}cfu – colony-forming units

The bioburden of tested masks ranged from 9.4 cfu/g to 63.9 cfu/g. The average total bioburden for the tested medical masks was 28,5 cfu/g.

Breathability (differential pressure) test

The results of the breathability (differential pressure) test for the medical masks are given in Table 3.

Table 3. The results of differential pressure tests for evaluated medical masks.

Sample tested	Differential pressure (Pa/cm ²)	Requirements of EN 14683:2019+AC
Mask no. 11	56.00	Differential pressure for particular types of medical masks should be: Typ I <40 Pa/cm ² Typ II <40 Pa/cm ² Typ IIR <60 Pa/cm ²
Mask no. 12	51.51	
Mask no. 13	48.41	
Mask no. 14	49.67	
Mask no 15	50.86	

The differential pressure for evaluated medical masks ranged from 48.41 Pa/cm² to 56.00 Pa/cm².

RESULTS AND CONCLUSIONS

Evaluation of bacterial filtration efficiency

The average filtration efficiency of the bacterial aerosol *Staphylococcus aureus* ATCC 6538 for the medical masks tested was 99,8%, which means that **the tested masks meet the requirements for Type II and Type IIR medical face masks as described in EN 14683:2019+AC** as the bacterial filtration efficiency should amount to $\geq 98\%$.

Evaluation of total bioburden

The average total bioburden for the tested medical masks was 28.5 cfu/g, which means that **the tested masks meet the requirements for Type I, Type II and Type IIR medical face masks as described in EN 14683:2019+AC**, for which the total bioburden should be ≤ 30 cfu/g.

Evaluation of differential pressure

The differential pressure of the examined medical masks was in the range of 48.41 – 56.00 Pa/cm². Therefore **the masks tested met the requirements of EN 14683:20019+AC for Type IIR medical face masks**, for which the differential pressure should be < 60 Pa/cm². However, met the requirements for masks **Type I and Type II** (differential pressure < 40 Pa/cm²).

Note:

The report has been prepared for the above mentioned the Ordering Party. No part of the report may be duplicated by other entities without the written consent of the Ordering Party and the Performer (i.e. CIOP-PIB).

The results relate only to the samples tested.

REFERENCES

EN 14683:2019+AC: Medical face masks - Requirements and test