



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

Department of Chemical, Aerosol and Biological Hazards
Biological Hazards Laboratory

TEST REPORT

Contract to perform testing No.: 1084/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:	Medical Protection Sp. z o.o. Sp. K. ul. Biały Kamień 2/U6 02-593 Warszawa
Date of start 31.07.2020 r.	Date of end 6.08.2020 r.
	Name and surname
Main performer	Professor Rafał L. Górny, PhD, D.Med.Sc.
Performers	Agata Stobnicka-Kupiec, BEng, PhD Małgorzata Gołofit-Szymczak, PhD Anna Ławniczek-Wałczyk, PhD Marcin Cyprowski, PhD, D.Med.Sc. Agnieszka Brochocka, BEng, PhD, DSc Krzysztof Makowski, MSc

KIEROWNIK ZAKŁADU
Zagrożenia Chemicznych, Pyłowych i Biologicznych

Małgorzata Pośniak
dr Małgorzata Pośniak

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AIM OF THE TESTS

The aim of the study was to assess the bacterial filtration efficiency (BFE), microbiological cleanliness (bioburden) and breathability (differential pressure) of one batch of medical face masks supplied by the company Medical Protection Sp. z o.o. Sp. K., ul. Biały Kamień 2/U6, 02-593 Warszawa.

TEST MATERIAL

The material for the study consisted of 15 medical masks made of non-woven fabric measuring 17.1×9.3 cm, in blue colour with rubber bands.

METHODOLOGY

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

- filtration efficiency of *Staphylococcus aureus* strain ATCC 653 - 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. Results of bacterial filtration efficiency tests of non-woven fabric from medical masks tested.

Sample tested	Total number of bacteria (cfu [*])	Bacterial filtration efficiency (%)	Requirements of EN 14683:2019+AC
Negative control (the mean of the two negative control runs)	0	-	Bacterial filtration efficiency for particular types of medical masks should be: Type I ≥ 95 % Type II ≥ 98 % Type IIR ≥ 98 %
Positive control (the mean of the two positive control runs)	9859	-	
Mask no. 1	106	98.9	
Mask no. 2	127	98.7	
Mask no. 3	191	98.1	
Mask no. 4	106	98.9	
Mask no. 5	106	98.9	

^{*}) cfu – colony-forming units

The bacterial filtration efficiency for the tested medical masks was in the range of 98.1% to 98,9%.. The average filtration efficiency is 98.7%.

Microbiological cleanliness (bioburden) test

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

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

Sample tested	Mass (g)	Total number of bacteria on the filter (cfu)	Total number of the fungi on the filter (cfu)	Total number of micro-organisms (cfu/mask)	Total number of micro-organisms (cfu/g)	Requirements of EN 14683:2019+AC
Mask no. 6	3.4	12	1	39	11.5	Total bioburden for particular types of medical masks should be: Type I, Type II and Type IIR ≤ 30 cfu/g
Mask no. 7	3.5	17	1	54	15.4	
Mask no. 8	3.4	19	1	60	17.6	
Mask no. 9	3.4	25	1	78	22.9	
Mask no. 10	3.5	15	1	48	13.7	

^{*)} cfu – colony-forming units

The total bioburden of medical masks ranged from 11,5 jtk/g to 22,9 jtk/g. The average total bioburden for the tested non-woven fabric from medical masks was equal to 16.2 cfu/g.

Breathability (differential pressure) test

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

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

Sample tested	Differential pressure (Pa/cm ²)	Requirements of EN 14683:2019+AC
Mask no. 11	32.04	Differential pressure for particular types of medical masks should be: Type I <40 Pa/cm ² Type II < 40 Pa/cm ² Type IIR < 60 Pa/cm ²
Mask no. 12	32.73	
Mask no. 13	33.67	
Mask no. 14	34.08	
Mask no 15	33.22	

INTERPRETATION OF RESULTS AND CONCLUSIONS

Evaluation of bacterial filtration efficiency

The filtration efficiency for which medical masks of the bacterial aerosol *Staphylococcus aureus* ATCC 6538 for the tested equals 99.7%, which **means that the tested masks meet the requirements for Type I and Type IIR** medical face masks provided in EN 14683:2019+AC as the bacterial filtration efficiency should amount to $\geq 98\%$.

Bioburden

The average total bioburden for the medical masks was 16,2 jtk/g. **Thus the tested medical face masks meet the requirements of EN 14683:20019+AC for Type I, Type II and Type IIR** (bioburden should amount to ≤ 30 cfu/g).

Evaluation of differential pressure

The differential pressure of the examined medical masks was in the range of 32,04 – 34,08 Pa/cm². Therefore **the tested masks meet the requirements of EN 14683:20019+AC for Type I and Type II medical face masks**, for which the differential pressure should amount to <40 Pa/cm² and **Type IIR** (differential pressure should amount to <60 Pa/cm²).

Comments:

The report has been prepared for the above mentioned Customer. No part of the report may be reproduced by other entities without the written agreement of the Customer and the Research Contractor (i.e. CIOP-PIB).

The results obtained refer only to the tested samples.

REFERENCES

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