

[the translator's comments are made in square brackets]

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CENTRAL INSTITUTE FOR LABOUR PROTECTION

NATIONAL RESEARCH INSTITUTE

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Department of Chemical, Biological and Aerosol Hazards

No. 1264/PZ-TSB-COV/2020/NC

RE: Test of medical masks in order to prove their conformity with the standard EN 14683:2019+AC regarding the effectiveness of filtration of bacterial strains, microbiological purity and breathing resistance. Medical masks series Poland C PTAK.

ORDERING PARTY: PTAK Warsaw Expo Sp. z o.o.
ul. Aleja Katowicka 62
05-830 Nadarzyn

Commencement date: 07/09/2020
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The report is made on 6 (six) pages.

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TEST OBJECTIVE

The objective of the test was to assess the effectiveness of filtration of bacterial strains, microbiological purity (bioburden) and breathing resistance (differential pressure) of one batch of medical masks submitted by the company: PTAK Warsaw Expo Sp. z o.o., ul. Aleja Katowicka 62, 05-830 Nadarzyn.

MATERIAL FOR TESTING

Type of sample	Lot/batch No.	Colour	Dimensions	The number of items	Type of material	Additional elements
Three-layer medical mask	Medical mask series Poland C PTAK	white	17x10	15	non-woven fabric	white ear loop

TEST METHODOLOGY

The tests were conducted in line with the guidelines in the European standard EN 14683:2019+AC regarding:

- effectiveness of filtration of bacterial strains *Staphylococcus aureus* ATCC 6538 – as per Annex B
- microbiological purity (bioburden) - as per Annex D,
- breathing resistance (differential pressure) - as per Annex C

The flow rate of the bioaerosol stream at the inlet to the measuring set pump during the tests was 28.3 dm³ / min. In accordance with the recommendations of the EN 14683:2019+AC standard, each mask was exposed to the aerosol from the inside during the test. Each mask has a tested area of 52.78 cm².

TEST RESULTS

Efficiency of filtration of bacterial strains

Table 1 shows the total number of bacteria that penetrate the mask along with the bacterial filtration efficiency calculated according to the EN 14683:2019+AC standard for the tested medical masks of the Poland C PTAK series.

Table 1. Results of the bacterial filtration efficiency test regarding the tested medical masks of the Poland C PTAK series.

Tested sample	The total number of bacteria (colony forming units)	Bacteria filtration efficiency	Requirements as per EN 14683:2019+AC
Negative control (the mean value of the two measurements)	0	-	The filtration efficiency for each medical mask type shall stand at:

Positive control (the mean value of the two measurements)	9795	-	Type I ≥ 95% Type II ≥ 98% Type IIR ≥ 98%
Mask 1	0	>99.9	
Mask 2	0	>99.9	
Mask 3	14	99.9	
Mask 4	0	>99.9	
Mask 5	21	99.8	

cfu – colony forming units

The effectiveness of filtration of bacterial for the tested mask was from 99.8% do > 99.9%.

Microbiological purity (bioburden) test

Table 2 shows the results of the microbiological purity test regarding the tested medical masks of the Poland C PTAK series.

Table 2. Results of the microbiological purity test regarding the tested medical masks.

Tested sample	Weight (g)	Total number of bacteria on the filter (cfu*)	Total number of fungi on the filter (cfu)	Total number of microbes (cfu/mask)	Total number of microbes (cfu/g)	Requirements as per PN-EN 14683:2019+AC
Mask 6	2.3	19	4	69	30.0	Bioburden for each medical mask type shall stand at: Type I, Type II and Type IIR ≤ 30 cfu/g
Mask 7	2.3	2	4	18	7.8	
Mask 8	2.3	5	7	36	15.7	
Mask 9	2.3	10	5	45	19.6	
Mask 10	2.3	5	3	24	10.4	

* cfu – colony forming units

The bioburden of the masks ranged from 7.8 cfu/g to 30.0 cfu/g.

Breathing resistance (differential pressure) test

Table 3 shows the result of the breathing resistance (differential pressure) test regarding the tested medical masks of the Poland C PTAK series.

Table. 3 Result of the differential pressure test for the testes medical masks.

Tested sample	Differential pressure (Pa/cm ²)	Requirements as per EN 14683:2019+AC	Requirements as per EN 14683:2005
Mask 11	32.98	Differential pressure for each medical mask type shall stand at: Type I <40 Pa/cm ² Type II <40 Pa/cm ² Type IIR <60 Pa/cm ²	Differential pressure for each medical mask type shall be lower than: Type I – 29.4 Pa/cm ² Type IR – 49.0 Pa/cm ² Type II – 29.4 Pa/cm ² Type IIR – 49.0 Pa/cm ²
Mask 12	33.67		
Mask 13	39.31		
Mask 14	35.55		
Mask 15	33.55		

INTERPRETATION OF RESULTS AND CONCLUSIONS

Assessment of effectiveness of filtration of bacterial strains

Filtration efficiency of bacterial aerosol of *Staphylococcus aureus* ATCC 6538 for the tested medical masks of the Polska C PTAK series range from 99.8% to > 99.9%, which means that **the tested masks conform with the requirements for Type I, Type II, Type IIR medical masks** included in the EN 14683:2019+AC standard, for which the effectiveness of microbial filtration should be appropriately $\geq 95\%$ (Type I) and $\geq 98\%$ (Type II, Type IIR).

Assessment of bioburden

The bioburden of medical masks of the Polska C PTAK series ranged from 7.8 cfu/g to 30.0 cfu/g, which means that **the tested conform with the requirements for Type I, Type II and Type IIR medical masks** for which bioburden shall stand at ≤ 30 cfu/g.

Assessment of breathing resistance

The differential pressure of the tested medical masks of Polska C PTAK series range from 33.55-39.31 Pa/cm², which means that the **tested masks conform with the requirements of the standard EN 14683:2019+AC for medical masks of Type I and Type II**, for which the differential pressure shall stand at ≤ 40 Pa/cm² **and Type II R** for which the differential pressure shall stand at ≤ 60 Pa/cm²

The tested medical masks of Polska C PTAK series **conform with the requirements of the standard EN 14683:2005 for medical masks of Type I R and Type II R**, for which the differential pressure shall stand at ≤ 49 Pa/cm²

Comments

The report was made for the above-mentioned Ordering Party. No part of the report may be copied by other entities without prior written consent of the Ordering Party and the Test Performer (i.e. CENTRAL INSTITUTE FOR LABOUR PROTECTION – NATIONAL RESEARCH INSTITUTE).

The results obtained are valid for the tested samples only.

BIBLIOGRAPHY

EN 14683:2019+AC [*text in English*] Medical face masks – Requirements and test