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Department of Chemical, Dust and Biological Hazards

No 258/PZ-TSB-COV/2020/NC

SUBJECT:	Testing of medical masks in accordance with EN 14683:2019+AC for bacterial strain filtration efficiency, microbiological purity and respiratory resistance
ORDERER:	EUROPROFIL Sp. z o.o. ul. Zielona 11, 11-015 Olsztynek
Starting date 14.04.2020	End date 21.04.2020

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RESEARCH OBJECTIVE

The aim of the study was to assess the effectiveness of filtration of bacterial strains, microbiological purity (microbiological load) and respiratory resistance (differential pressure) of one batch of medical masks supplied by EUROPROFIL Sp. z o.o., ul. Zielona 11, 11-015 Olsztynek.

TEST MATERIAL

The test material was 15 medical masks measuring 9.5 x 17.5 cm in blue non-woven fabric with rubber bands.

METHODOLOGY

The tests were carried out in accordance with the guidelines included in European standard EN 14683:2019+AC in the scope:

- filtration efficiency of Staphylococcus aureus ATCC 653 strains - according to Annex B,
- microbiological purity (microbiological load) - according to Annex D,
- respiratory resistance (differential pressure) - according to Annex C.

TEST RESULTS

Tests of filtration efficiency of bacterial strains

Table 1 shows the total number of bacteria that permeate the medical mask together with the filtration efficiency calculated according to EN 14683:2019+AC.

Table 1. Results of medical mask filtration efficiency tests.

Sample tested	Total number of bacteria (cfu*)	Bacterial filtration efficiency (%)	Requirements according to EN 14683:2019+AC
Negative control (average value of two measurements)	0	-	The filtration efficiency of the individual types of medical masks should equal: Type I >95 % Type II >98 % Type IIR >98 %
Positive control (average value of two measurements)	509	-	
Mask no. 1	7	98,6	
Mask no. 2	7	98,6	
Mask no. 3	7	98,6	
Mask no. 4	7	98,6	
Mask no. 5	7	98,6	

cfu - colony-forming units

The average bacteria filtration efficiency for the tested masks equals 98.6%.

Microbiological purity test (microbiological load)

Table 2 shows the results of the microbiological loading of medical masks.

Table 2. Results of examination of microbiological load of medical masks.

Sample tested	Mass (g)	Total number of bacteria on the filter (cfu)	Total number of moulds on the filter (cfu)	Total number of microorganisms (cfu/mask)	Total number of microorganisms (cfu/g)	Requirements according to EN 14683:2019+AC
Mask no. 6	2,8	2	1	9	3,2	The microbiological load for each type of medical mask should equal: Type I, Type II and Type IIR <30 cfu/g
Mask no. 7	2,7	8	0	24	8,9	
Mask no. 8	2,4	9	0	27	11,3	
Mask no. 9	2,9	2	2	12	4,1	
Mask no. 10	2,8	6	0	18	6,4	

* cfu - colony-forming units

The microbiological load of masks ranged from 3.2 cfu/g to 11.3 cfu/g. The average microbiological load of the masks tested was 6.8 cfu/g.

Respiratory resistance test (differential pressure)

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

Table 3. Differential pressure test results for medical masks.

Sample tested	Differential pressure (Pa/cm^2)	Requirements according to EN 14683:2019+AC
Mask no. 11	3,15	The differential pressure for each type of medical mask shall be as follows: Type I <40 Pa/cm^2 Type II <40 Pa/cm^2 Type IIR <60 Pa/cm^2
Mask no. 12	3,06	
Mask no. 13	3,42	
Mask no. 14	3,12	
Mask no. 15	2,86	

INTERPRETATION OF RESULTS AND CONCLUSIONS

Evaluation of filtration efficiency of bacterial strains

The average filtration efficiency of *Staphylococcus aureus* ATCC **6538** bacterial aerosol for medical masks was **98.6%**, which means that **the tested masks meet the requirements for Type II medical masks** as defined in **EN 14683:2019+AC**, for which the microbial filtration efficiency should be **>95%**.

Microbiological load assessment

The average microbiological load of the masks was 6.8 cfu/g, which means that **the medical masks tested meet the requirements for Type I, Type II and Type IIR medical masks**, for which the microbiological load should be <30 cfu/g.

Evaluation of respiratory resistance

The differential pressure of the medical masks tested was in the range **3.64-3.96** Pa/cm², which means that **the masks tested meet the requirements of** EN 14683:20019+AC **for Type I and Type II medical masks**, for which the differential pressure should be <**40** Pa/cm², **and Type IIR** (differential pressure <**60** Pa/cm²).

REFERENCES

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