CENTRAL INSTITUTE FOR LABOUR PROTECTION
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Department of Chemical, Aerosol and Biological Hazards
Biological Hazards Laboratory

TEST REPORT

Contract to perform testing No.: **693/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. Medical mask Type II non-sterile with rubber band, test batch 013 0042020.
ORDERING PARTY:	TW PLAST Sp. z o. o. ul. Puławska 38 05-500 Piaseczno

Date of start 01.06.2020 — Date of end 09.06.2020

The test report consists of 5 (five) pages.

	Name and surname
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Table of contents

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 medical masks Type II, non-sterile with rubber band, test batch 013 0042020 supplied by the company TW PLAST Sp. z o. o., ul. Puławska 38, 05-500 Piaseczno.

TEST MATERIAL

The material for the study consisted of 15 medical masks (test batch 013 0042020) made of non-woven fabric measuring 17.4×9.5 cm, in white 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)	2890	-	
Mask no. 1	21	99,3	
Mask no. 2	7	99,8	
Mask no. 3	14	99,5	
Mask no. 4	7	99,8	
Mask no. 5	7	99,8	

*) cfu – colony-forming units

The average bacterial filtration efficiency for the tested medical masks was from 99,3% to 99,8%. The average bacterial filtration efficiency was 99,6%.

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	2,3	2	0	6	2,6	Total bioburden for particular types of medical masks should be: Type I, Type II and Type IIR ≤ 30 cfu/g
Mask no. 7	2,2	2	0	6	2,7	
Mask no. 8	2,3	0	0	0	0,0	
Mask no. 9	2,2	5	0	15	6,8	
Mask no. 10	2,3	3	0	9	3,9	

*) cfu – colony-forming units

The total bioburden of medical masks ranged from 0 cfu/g to 6,8 cfu/g. The average total bioburden for the tested non-woven fabric from medical masks was equal to 3,2 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	25,67	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	25,92	
Mask no. 13	24,20	
Mask no. 14	25,63	
Mask no 15	26,16	

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 99,6%, which **means that the tested masks meet the requirements for Type II and Type IIR** medical face masks provided in EN 14683:2019+AC as the bacterial filtration efficiency should amount to ≥ 98%.

Bioburden

The average total bioburden for the medical masks was 3,2 cfu/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 24,20 – 26,16 Pa/cm^2. Therefore **the tested masks meet the requirements of EN 14683:20019+AC for Type I and Type II**, for which the differential pressure should amount to <40 Pa/cm^2 and for **Type IIR (**differential pressure should be <40 Pa/cm^2)

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