Medprotex BV

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Nederland

Your notice of	Your reference	Date
15-06-2020		07-10-2020

Analysis Report 2020-10

Required tests			SOP used
EN 14683 (2019) + AC (2019)	EN 14683 (2019) - annex B (2019)	Bacterial filtration efficiency	AMIBM SOP 2.0; Date 29.6.2020

Identification number	Information given by the client	Date of receipt
	Medprotex Light Non-Medical	15-06-2020

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KvK nr.: 50169181

Reference: Medprotex Light Non-Medical

Bacterial filtration efficiency

Date of ending the test	08.07.2020
Standard used	EN 14683 (2019) - annex B (2019)
Product standard	EN 14683 (2019) + AC (2019)
SOP version used	AMIBM SOP 2.0; Date 29.6.2020
Number of tested masks	5
BFE area tested	±49 cm^2
Mask conditioning	≥4 h at 21 ± 5° C and 85 ± 5% RH
Mask/bacteria contact side	Inner side
Challenge bacterial strain used	*Staphylococcus aureus* ATCC6538
Bacterial challenge per test	1700-3000 CFU
Total test time	1 min. challenge delivery + 1 min. without challenge (continuous air flow)
Flow rate	28.3 l/min
Positive control	Tests performed without filter in air stream
Negative control	Test performed without bacterial challenge
Deviation from the standard	

Results

B = Bacterial filtration efficiency (%)

C = Mean of the total plate counts for the positive control runs

T = Total count for the tested mask specimen

$$B = \frac{(C - T)}{C} x\ 100$$

Mask #	B (%)
1	>99.9*
2	>99.9*
3	>99.9*
4	>99.9*
5	>99.9*

*no detected colony on any TSA sampler plates

Mean particle size of the bacterial aerosol challenge: 3.0 µm

Controls

Mean positive controls 1835 CFU
Negative control < 1 CFU

This test report is valid for products used in relation to the current Covid-19 health crisis and for products which are not entering the regular distribution channels. Cfr Commission Recommendation (EU) 2020/403 of13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat