



Order-nr : 862685

Ostrichoo International B.V.
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Omschrijving	:	FACE MASK 50 STUKS			
Productcode	:	2020202			
Uw project-nr.	:	20200901			
Ontvangstdatum	:	01-09-2020	Monsternamedatum	:	
Rapportdatum	:	21-09-2020	Inzetdatum microbiologie	:	07-09-2020
Monsternemer	:		Monstertransport	:	Post/Koerier
Verpakking	:	Orginele verpakking	Monstertemperatuur	:	Kamertemperatuur
Verzegeld	:	N	Monsterconditie	:	Monster en verpakking intact

Bepaling	Resultaat
Bacterial Filtration Efficiency (BFE)	
I 35000 Testing BFE (n=5) (equiv. NEN-EN 14683+C1)	
I 35050 Test conditions	
I 35051 Dimensions of test specimens (width x height)	a 17,5 x 9,5 cm
I 35052 Size of the area tested (width x height)	48,0 cm ²
I 35053 Side facing the aerosol	Face side
I 35054 Flow rate during testing	28.3 ± 0.3 L/min
I 35060 Mean of the total plate counts of the two positive controls	a 2.959 cfu
I 35070 Mean plate count of the negative controls	a 0 cfu
I 35100 Bacterial Filtration Efficiency (BFE, equiv. NEN-EN 14683+C1)	
I 35101 BFE specimen 1	a 99,6 %
I 35102 BFE specimen 2	a > 99,7 %
I 35103 BFE specimen 3	a 99,7 %
I 35104 BFE specimen 4	a > 99,8 %
I 35105 BFE specimen 5	a > 99,9 %
I 35199 Average BFE	a > 99,7 %

Breathability	
E 35330 Differential pressures (dP)	
E 35331 dP specimen 1, area 1	19,8 Pa/cm ²
E 35340 average dP specimen 1	19,6 Pa/cm ²
E 35341 dP specimen 2, area 1	18,8 Pa/cm ²
E 35350 average dP specimen 2	19,2 Pa/cm ²
E 35351 dP specimen 3, area 1	18,4 Pa/cm ²
E 35360 average dP specimen 3	20,4 Pa/cm ²
E 35361 dP specimen 4, area 1	20,0 Pa/cm ²
E 35370 average dP specimen 4	19,9 Pa/cm ²



E 35371	dP specimen 5, area 1	18,2	Pa/cm ²
E 35380	average dP specimen 5	19,8	Pa/cm ²

Splash resistance

I 35600	Splash resistance (equiv. ISO 22609:2004)		
I 35611	Splash resistance specimen 1	Pass	16 kPa
I 35612	Splash resistance specimen 2	Pass	16 kPa
I 35613	Splash resistance specimen 3	Pass	16 kPa
I 35614	Splash resistance specimen 4	Fail	16 kPa
I 35615	Splash resistance specimen 5	Pass	16 kPa
I 35616	Splash resistance specimen 6	Pass	16 kPa
I 35617	Splash resistance specimen 7	Pass	16 kPa
I 35618	Splash resistance specimen 8	Pass	16 kPa
I 35619	Splash resistance specimen 9	Pass	16 kPa
I 35620	Splash resistance specimen 10	Pass	16 kPa
I 35621	Splash resistance specimen 11	Pass	16 kPa
I 35622	Splash resistance specimen 12	Pass	16 kPa
I 35623	Splash resistance specimen 13	Pass	16 kPa
I 35624	Splash resistance specimen 14	Pass	16 kPa
I 35625	Splash resistance specimen 15	Pass	16 kPa
I 35626	Splash resistance specimen 16	Pass	16 kPa
I 35627	Splash resistance specimen 17	Pass	16 kPa
I 35628	Splash resistance specimen 18	Pass	16 kPa
I 35629	Splash resistance specimen 19	Pass	16 kPa
I 35630	Splash resistance specimen 20	Pass	16 kPa
I 35631	Splash resistance specimen 21	Pass	16 kPa
I 35632	Splash resistance specimen 22	Fail	16 kPa
I 35633	Splash resistance specimen 23	Pass	16 kPa
I 35634	Splash resistance specimen 24	Pass	16 kPa
I 35635	Splash resistance specimen 25	Pass	16 kPa
I 35636	Splash resistance specimen 26	Pass	16 kPa
I 35637	Splash resistance specimen 27	Fail	16 kPa
I 35638	Splash resistance specimen 28	Pass	16 kPa
I 35639	Splash resistance specimen 29	Pass	16 kPa
I 35640	Splash resistance specimen 30	Pass	16 kPa
I 35641	Splash resistance specimen 31	Pass	16 kPa
I 35642	Splash resistance specimen 32	Pass	16 kPa

Microbial cleanliness (Bioburden)

I 35211	Total bioburden specimen 1	a,Q	< 30	cfu/mask
	Opmerking : Ind. 7 cfu, Reanalysis			
I 35212	Total bioburden specimen 2	a,Q	< 30	cfu/mask
	Opmerking : Ind. 18 cfu, Reanalysis			
I 35213	Total bioburden specimen 3	a,Q	39	cfu/mask
	Opmerking : Reanalysis			
I 35214	Total bioburden specimen 4	a,Q	30	cfu/mask
	Opmerking : Reanalysis			





I 35215	Total bioburden specimen 5 Opmerking : Ind. 27 cfu, Reanalysis	a,Q	< 30	cfu/mask
I 35251	Total bioburden specimen 1 Opmerking : Ind. 5 cfu, Reanalysis	Q	< 8	cfu/g
I 35252	Total bioburden specimen 2 Opmerking : Ind. 5 cfu, Reanalysis	Q	< 8	cfu/g
I 35253	Total bioburden specimen 3 Opmerking : Reanalysis	Q	10	cfu/g
I 35254	Total bioburden specimen 4 Opmerking : Reanalysis	Q	8	cfu/g
I 35255	Total bioburden specimen 5 Opmerking : Ind. 7 cfu, Reanalysis	Q	< 8	cfu/g

Conclusion*

I 35290	Mask type based on BFE performance requirements for medical face masks is:	I/II/IIR
I 35390	Mask type based on differential pressure performance requirements for medical face masks is:	I/II/IIR
I 35690	Mask type based on splash resistance performance requirements for medical face masks is:	I/II/IIR
I 35280	Mask type based on bioburden performance requirements for medical face mask is: Opmerking : Reanalysis	I/II/IIR
I 35699	Mask type based on overall performance requirements for medical face masks is: Opmerking : Reanalysis	I/II/IIR

a) Dit analysesresultaat is mogelijk niet representatief voor de microbiologische samenstelling van het monster op het moment van monstername. (De tijd tussen bemonsteren en inzetten van deze analyse is langer dan maximaal toegestaan of niet bekend).

*) Performance requirements for medical face masks (acc. European Standard no. EN 14683:2019+AC):

Bacterial filtration efficiency (BFE) (%): Type I: ≥ 95 , Type II: ≥ 98 , Type IIR: ≥ 98
Differential pressure (Pa/cm²): Type I: < 40 , Type II: < 40 , Type IIR: < 60
Splash resistance pressure (kPa): Type I: n.a., Type II: n.a., Type IIR: ≥ 16.0
Microbial cleanliness (cfu/g): Type I: ≤ 30 , Type II: ≤ 30 , Type IIR: ≤ 30

Remark:

Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations.

Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

This certificate of analysis is a test report. The tested samples are part of the mentioned batch/lot number. Batch validation is not the scope of this report.

z) Result taken from Nutrilab CoA no.

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Startdatum analyse: 07-09-2020, einddatum: 21-09-2020.





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Analysrapport

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De analysesresultaten hebben alleen betrekking op het monster zoals ontvangen. Nadere informatie over een toegepaste methode en de bijbehorende meetonzekerheid is opvraagbaar bij Customer Service.

De interpretaties van analysesresultaten vermeld op dit rapport vallen buiten de scope van de accreditatie.

Met de eenheid % wordt m/m% bedoeld, tenzij anders vermeld.

Nutrilab is niet verantwoordelijk voor de gegevens verstrekt door de opdrachtgever.

Dit certificaat mag zonder uitdrukkelijk schriftelijke toestemming van Nutrilab BV niet anders dan in zijn geheel worden gereproduceerd.

i/o


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De betekenis van de gebruikte tekens is:

- Q Analyse met RVA-accreditatie (ISO/IEC 17025)
- I Analyse door Nutrilab BV uitgevoerd
- E Analyse door Nutrilab BV uitbesteed

Rapportversie 04: vervangt alle voorgaande versies

