



ECO Textieldruk B.V.

Wasaweg 16a-16B  
9723 JD GRONINGEN

Omschrijving	:	HOLLANDE MONDKAPJES MET SPECIAAL FILTER TYPE IIR		
Uw project-nr.	:	20201014		
Ontvangstdatum	:	14-10-2020	Monsternamedatum	: 13-10-2020 15:00
Rapportdatum	:	03-11-2020	Inzetdatum microbiologie	: 20-10-2020
Monsternemer	:		Monstertransport	: Post/Koerier
Verpakking	:	Orginele verpakking	Monstertemperatuur	: Kamertemperatuur
Verzegeld	:	N	Monsterconditie	: Monster en verpakking intact

Bepaling	Resultaat
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### 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 <sup>2</sup>
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	2.599	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	%
I 35102	BFE specimen 2	a	> 99	%
I 35103	BFE specimen 3	a	> 99	%
I 35104	BFE specimen 4	a	> 99	%
I 35105	BFE specimen 5	a	> 99	%
I 35199	Average BFE	a	> 99	%

### Breathability

E 35330	Differential pressures (dP)			
E 35331	dP specimen 1, area 1		33,3	Pa/cm <sup>2</sup>
E 35340	average dP specimen 1		37,0	Pa/cm <sup>2</sup>
E 35341	dP specimen 2, area 1		39,8	Pa/cm <sup>2</sup>
E 35350	average dP specimen 2		37,8	Pa/cm <sup>2</sup>
E 35351	dP specimen 3, area 1		32,2	Pa/cm <sup>2</sup>
E 35360	average dP specimen 3		36,4	Pa/cm <sup>2</sup>
E 35361	dP specimen 4, area 1		31,8	Pa/cm <sup>2</sup>
E 35370	average dP specimen 4		35,0	Pa/cm <sup>2</sup>
E 35371	dP specimen 5, area 1		29,8	Pa/cm <sup>2</sup>





E 35380 average dP specimen 5 33,6 Pa/cm<sup>2</sup>

### 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	Pass	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	Pass	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	Pass	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	Fail	16 kPa
I 35641	Splash resistance specimen 31	Pass	16 kPa
I 35642	Splash resistance specimen 32	Pass	16 kPa

### Microbial cleanliness (Bioburden)

I 35200	Microbial cleanliness (Bioburden) (equiv. NEN-EN 14683+C1)		
I 35210	Total bioburden per individual mask		
I 35211	Total bioburden specimen 1	Q < 30. ind. 24	cfu/mask
I 35212	Total bioburden specimen 2	Q < 30. ind. 24	cfu/mask
I 35213	Total bioburden specimen 3	Q < 30. ind 15	cfu/mask
I 35214	Total bioburden specimen 4	Q < 12	cfu/mask
I 35215	Total bioburden specimen 5	Q < 30. ind. 21	cfu/mask
I 35250	Total bioburden per gram		
I 35251	Total bioburden specimen 1	Q < 10. ind 8	cfu/g



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I 35252	Total bioburden specimen 2	Q	< 10. ind. 8	cfu/g
I 35253	Total bioburden specimen 3	Q	< 10. ind. 5	cfu/g
I 35254	Total bioburden specimen 4	Q	< 4	cfu/g
I 35255	Total bioburden specimen 5	Q	< 10. ind. 7	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:	I/II/IIR
I 35699	Mask type based on overall performance requirements for medical face masks is:	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:  $\geq 95$ , Type II:  $\geq 98$ , Type IIR:  $\geq 98$   
Differential pressure (Pa/cm<sup>2</sup>): Type I:  $< 40$ , Type II:  $< 40$ , Type IIR:  $< 60$   
Splash resistance pressure (kPa): Type I: n.a., Type II: n.a., Type IIR:  $\geq 16.0$   
Microbial cleanliness (cfu/g): Type I:  $\leq 30$ , Type II:  $\leq 30$ , Type IIR:  $\leq 30$

### 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.

Startdatum analyse: 20-10-2020, einddatum: 03-11-2020.

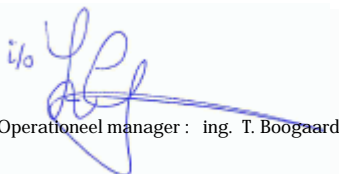
De analysesresultaten hebben alleen betrekking op het monster zoals ontvangen. Nadere informatie over een toegepaste methode en de bijbehorende meetonzekerheid is opvraagbaar bij Customer Service.

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.

  
Operationeel manager : ing. T. Boogaard