Certificate of analysis

Order-no : 875491

Kiwa Nederland B.V.
Attn. Mrs. C. Geenen
Wilmersdorf 50
7327 AC APELDOORN

Description	:	MEDIZINISCHER MUND & NASENSCHUTZ			
Client project-no	:	200901945			
Sample received	:	02-10-2020	Sample date	:	01-10-2020
Report date	:	15-10-2020	Start date microbiology	:	06-10-2020
Sampling	:		Sample delivery	:	Nutrilab BV
Packing	:	Original	Sample temperature	:	Room temperature
Sealed	:	No	Sample condition	:	Sample and packing intact
Remark	:	Order number : CG-201001-02			

Test		Result	
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)	17,5 x 9,5	cm
I 35052	Size of the area tested (width x height)	48.0	cm²
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	1,972	cfu
I 35070	Mean plate count of the negative controls	0	cfu
I 35100	Bacterial Filtration Efficiency (BFE, equiv. NEN-EN 14683+C1)		
I 35101	BFE specimen 1	> 99.7	%
I 35102	BFE specimen 2	> 99.7	%
I 35103	BFE specimen 3	> 99.7	%
I 35104	BFE specimen 4	> 99.7	%
I 35105	BFE specimen 5	> 99.7	%
I 35199	Average BFE	> 99.7	%
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

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KvK 18114291
BTW NL002007654B01

Explanation of symbols:

Q RvA accreditated test (ISO / IEC 17025)
I Test performed by Nutrilab BV
E Test performed by sub-contractor

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		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		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 35200	Microbial cleanliness (Bioburden) (equiv. NEN-EN 14683+C1)			
I 35210	Total bioburden per individual mask			
I 35211	Total bioburden specimen 1	Q	< 30	cfu/mask
I 35212	Total bioburden specimen 2	Q	< 12	cfu/mask
I 35213	Total bioburden specimen 3	Q	< 12	cfu/mask
I 35214	Total bioburden specimen 4	Q	< 12	cfu/mask
I 35215	Total bioburden specimen 5	Q	< 30	cfu/mask
I 35250	Total bioburden per gram			
I 35251	Total bioburden specimen 1	Q	< 8	cfu/g
I 35252	Total bioburden specimen 2	Q	< 3	cfu/g
I 35253	Total bioburden specimen 3	Q	< 3	cfu/g
I 35254	Total bioburden specimen 4	Q	< 3	cfu/g
I 35255	Total bioburden specimen 5	Q	< 8	cfu/g

Conclusion*

I 35290	Mask type based on BFE performance requirements for medical face masks is:	I/II/IIR

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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

*) 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.

Start date analysis: 06-10-2020, end date: 15-10-2020.

i/o

Operational manager : ing. T. Boogaard

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RvA TESTING L136