



E Q U I L I B R I U M

laboratório de controlo de qualidade e de processos



Test Report No.:20211947

Version :1.0

Ambit: Determinations in samples of Medical devices - Face Masks

Definitive Report

Requester: Farbalstav s.r.o.

Address: Celladice 417, 95103 - 95103 Celadice - SLOVENSKO

Designation of Sample: FAR17595NANO

SAMPLING

Date: 05/02/2021 Name of Response: Cliente
Time Collected: --- V/ Reference: FAR17595NANO
Analysis Type: MB+FQ Methods of Reap: ---
Lot: FAR17595NANO Expiration: ---

ANALYSIS

Entry Date: 05/02/2021 Period of analysis: 05/02/2021 a 12/02/2021 Ref. Sample: 20211947

Description	Methods	Unit	Results/Uncertainty	Lim. lei	VMR
Visual Inspection	MI 176 *	-	Suitable	-	-
Bacterial filtration efficiency	EN14683:2019+AC 2019-5.2.2	%	99.6 ±1.8%	TypeI ≥95% TypeII ≥98%	TypeIIR ≥98%
Breathability (Diferencial pressure)	EN14683:2019+AC 2019-5.2.3	Pa/cm2	42.9 ±8.7%	TypeI <40 Type II <40	TypeIIR <60
Microbial cleanliness (Bioburden)	EN ISO 11737-1:2018	UFC/g	9 ±20%	Type I ≤30 Type II ≤30	TypeIIR ≤30
Splash resistance pressure	ISO 22609:2004	---	10.6 /specimens "pass":0, "fail":32	Type I and II not required	Type IIR ≥16.0
Head harness strength	MI 177 *	-	Resists	-	-

APPRECIATION

Read the LimLei and VMR values, the values defined in Table I of EN 14683: 2019.

After comparison, the results obtained in the tests carried out with tabulated limits, the analyzed sample is NOT QUALIFIED.

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Description	Methods	Unit	Results/Uncertainty	Lim. lei	VMR
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REMARKS

BACTERIAL FILTRATION EFFICIENCY (Filtration) _EN14683:2019+AC 2019:

Condições teste: Temperatura e Humidade relativa // Test conditions: Temperature and Relative humidity: 21±5°C / 85± 5 %

Área de cada réplica/ Dimensions of the test specimens: 4.9cm² (5 réplicas/ test specimens)

Superfície da amostra testada/ Side of the test specimen facing the challenge aerossol: interna / intern

Air flow rate: 28.3 l/min.

MPS 3.1

Réplica 1, Réplica 2, Réplica 3, Réplica 4, Réplica 5 (%) // Test specimen 1 ,Test specimen 2,Test specimen 3,Test specimen 4,Test specimen 5 (%)

99.7

99.8

99.3

99.7

99.3

DIFFERENTIAL PRESSURE (Breathability) _EN14683:2019+AC 2019:

Condições teste: Temperatura e Humidade relativa // Test conditions: Temperature and Relative humidity: 21±5°C / 85± 5 %

Área de cada réplica/ Dimensions of the test specimens: 4.9cm² (5 réplicas/ 5 test specimens)

Número de áreas por réplica/ Number of áreas per specimen: 5 áreas por réplica (A,B,C,D,E)// 5 áreas for test specimen (A,B,C,D,E)

Superfície da amostra testada: Teste realizado com a direcção do fluxo do interior para o exterior. Localização lateral e central. // Number and general location of the areas of the mask the differential measurements were taken: Test performed with the direction of flow from the inside to the outside. Side and central location.

Air flow rate: 8L/min

Réplica 1 (área A,B,C,D,E), Réplica 2 (área A,B,C,D,E), Réplica 3 (área A,B,C,D,E), Réplica 4 (área A,B,C,D,E) Réplica 5 (área A,B,C,D,E)

//Test specimen 1 (área A,B,C,D,E), Test specimen 2 (área A,B,C,D,E),Test specimen 3 (área A,B,C,D,E), Test specimen 4 (área A,B,C,D,E), Test specimen 5 (área A,B,C,D,E)

Unidades (Pa/cm²)

42.9

43.9

43.9

41.8

41.8

SPLASH RESISTANCE PRESSURE _ISO 22609:2004:

Condições teste: Amostra pré-condicionadas pelo menos 4 horas a Temperatura e Humidade relativa de 21±5°C / 85± 5 %// Test conditions:

Samples pre-conditioned for at least 4 hoursat Temperature and Relative humidity: 21±5°C / 85± 5 %

Amostra expostas a um esguicho de 2 mL sangue sintético a diferentes pressões (baixa:10.6 KPa; média 16.0KPa; alta 21.3KPa), tendo como área alvo o centro da máscara // Samples exposed to a jet of 2mL synthetic blood at pressure (low: 10.6 KPa; medium: 16.0 KPa; high:

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21.3 KPa) aimed at the centre of the mask. Teste realizado à temperatura do laboratório de 21°C e 45% humidade relativa, após 60 segundos da remoção da câmara de condicionamento // Test performed at laboratory temperature of 21°C and 45% relative humidity, within 60 seconds after the mask was removed from the conditioning chamber Observação após 10+1 segundo da penetração do sangue do lado oposto da máscara // Observation after 10+1 second of blood penetration on the opposite side of the mask. Sangue sintético segundo o anexo B da ISO 22609: 2004 com tensão superficial de 42+2mN/m, lote L202013 // Synthetic blood according to Annex B of ISO 22609: 2004 with surface tension of 42 + 2mN / m, batch L202013 Número e localização geral das áreas: 32 / centro da amostra (Se passar no mínimo um teste de pressão média para 29 das 32 amostras, correspondendo a um AQL 4%, conforme a EN 14683: 2019 máscara tipo IIR) // Number and General location of the áreas: 32 test specimen / center (pass at least Medium pressure test for 29 out of 32 samples as minimum, corresponding to AQL 4%, according EN 14683: 2019 mask Type IIR) Quantidade de amostras: 32 // 32 test specimen Localização alvo de cada réplica //General location of the áreas: centro da amostra // center AQL 4%: passando no mínimo 29 das 32 amostras analisadas para a pressão testada, conforme a EN 14683: 2019 máscara tipo IIR) // pass at least Medium pressure test for 29 out of 32 samples as minimum, corresponding to AQL 4%, according EN 14683: 2019 mask Type IIR. Resultados: Pressão baixa // Low pressure (10.6KPa) _ amostras/specimen "pass", _ amostras/specimen "fail" Pressão média // médium pressure (16.0KPa) 32 amostras/specimen "pass", 0 amostras/specimen "fail"					
Amost1	Fail	Fail			
Amost2	Fail	Fail			
Amost3	Fail	Fail			
Amost4	Fail	Fail			
Amost5	Fail	Fail			
Amost6	Fail	Fail			
Amost7	Fail	Fail			
Amost8	Fail	Fail			
Amost9	Fail	Fail			
Amost10	Fail	Fail			
Amost11	Fail	Fail			
Amost12	Fail	Fail			
Amost13	Fail	Fail			
Amost14	Fail	Fail			
Amost15	Fail	Fail			
Amost16	Fail	Fail			
Amost17	Fail	Fail			
Amost18	Fail	Fail			

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Amot19	Fail	Fail			
Amot20	Fail	Fail			
Amot21	Fail	Fail			
Amot22	Fail	Fail			
Amot23	Fail	Fail			
Amot24	Fail	Fail			
Amot25	Fail	Fail			
Amot26	Fail	Fail			
Amot27	Fail	Fail			
Amot28	Fail	Pass			
Amot29	Fail	Pass			
Amot30	Fail	Pass			
Amot31	Fail	Pass			
Amot32	Fail	Pass			

MICROBIAL CLEANLINESS (Bioburden) _ EN ISO 11737-1:2018:

5 min shaker at 250rpm

Area of each test specimen: 5 test specimens

Mic30°C (3 days), Molds and yeasts 25°C (7 days)

Medida de Incerteza Expandida a um nível de confiança de 95%, k=2/ The expanded uncertainty at a confidence level of 95%, K=2: 20%

13

9

9

5

8

RESISTÊNCIA AO ELÁSTICO/ Head harness strength :

Verificação da Resistência a 5 ciclos de colocação e remoção, em 3 sujeitos de ensaio, com diferentes morfologias.

// Verification of resistance to 5 cycles of placement and removal, in 3 test subjects, with different morphologies.

Inspecção Visual/ Visual Inspection:

- Ajuste do clipe nasal // Nasal clip adjustment

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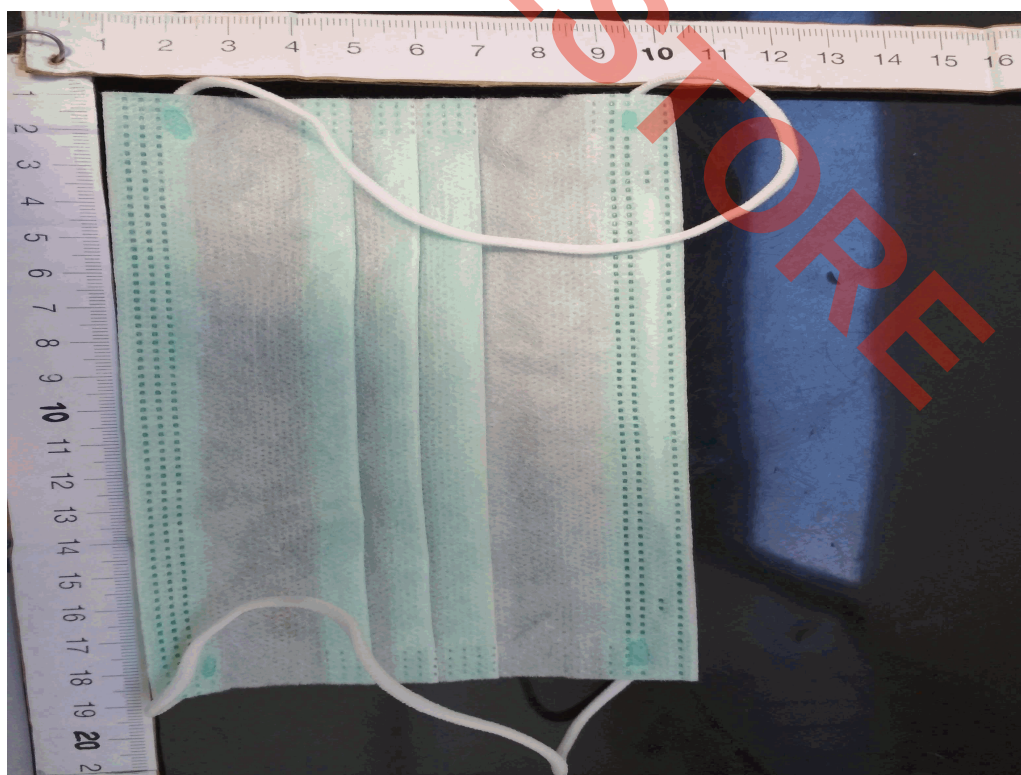
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Description	Methods	Unit	Results/Uncertainty	Lim. lei	VMR
- Rasgos // Rips, - Deformações // Deformations, - Desgaste // Wear, - Cobertura Facial // Facial Coverage					



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The indicated test with (*) isn't included on the ambit of accreditation of the laboratory

The Sampling is not included on the scope of accreditation.

NP: Norma Portuguesa; SMEWW: Standart Methods for the Examination of Water and Wastewater; ISO: Internacional Standard Organization; AFNOR: Association Francaise de Normalisation; LAE: L'Analyse des Eaux, Rodier 8e Édition; EN: Norma Europeia; DIN: Deutsches Institut für Normung; EPA: Environmental Protection Agency; ASTM: American Society for Testing and Materials; MI: Método Interno; N/A: Não aplicável; LQ: Limite de Quantificação; LD: Limite de Detecção; UFC: Unidades formadoras de colónias; VMR: Valor máximo recomendado; VMA: Valor máximo admissível; VP: Valor Paramétrico; Nos resultados obtidos por cálculo com base em resultados individuais, serão contabilizadas as parcelas quantificáveis desprezando as parcelas <LQ. Se todas as parcelas forem <LQ, o valor emitido será o LQ do método. O resultado pode ser apresentado com Medida de Incerteza Expandida, do Ensaio (não contemplando a da amostragem), a um nível de confiança de 95%, k=2, quando esta aparece associada ao resultado. O laboratório não contabiliza a incerteza no método na declaração de conformidade. A apresentação do resultado como $\leq$ ao LQ corresponde à faixa de guarda associada à incerteza do método. Os dados fornecidos pelo cliente são da sua responsabilidade (descritos no campo: "Colheitas" e "Designação Amostras"). Os resultados aplicam-se à amostra conforme recepcionada/Results apply to the sample as received.

Emission

Matosinhos, 17 de fevereiro de 2021

Laboratory Director

Maria Cristina Antão

Maria Cristina Antão, Dra.

(This Test Report was digitally signed)

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