Test Report No.:20217900

Version :1.0

Ambit: Determinations in samples of Medical devices - Face Masks

Definitive Report

Requester: Opharm sp Z o. o.
Adress: Pokrzywnica 62 - 99-120 Piatek, Poland

Designation of Sample: SANI-DM-02

SAMPLING

Date:	12/05/2021	**Name of Response:**	Cliente
Time Collected:	---	**V/ Reference:**	SANI-DM-02
Methods of Reap:	---	**Treatment:**	---
Lot:	MB001	**Expiration:**	---
Type:	Medical Device - Masks	**Size:**	Adult
Composition:	Polypropylene, black color		

ANALYSIS

Entry Date: 12/05/2021	**Period of analysis:** 12/05/2021 a 19/05/2021	**Ref. Sample:** 20217900

Description	Methods	Unit	Results/Uncertainty	Lim. lei	VMR
Visual Inspection	MI 176 *	-	Suitable	-	-
Bacterial filtration efficiency	EN14683:2019+AC 2019-5.2.2	%	99.1 ±1.8%	TypeI ≥95% TypeII ≥98%	TypeIIR≥98%
Breathability (Differencial pressure)	EN14683:2019+AC 2019-5.2.3	Pa/cm2	29,8 ±8.7%	TypeI<40 Type II<40	TypeIIR <60
Microbial cleanliness (Bioburden)	EN ISO 11737-1:2018	UFC/g	18 ±20%	Type I≤30 Type II≤30	TypeIIR≤30
Splash resistance pressure	ISO 22609:2004	---	16.0 /specimens "pass":32, "fail":0	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 QUALIFIED - TYPE IIR.

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Description	Methods	Unit	Results/Uncertainty	Lim. lei	VMR

REMARKS

BACTERIAL FILTRATION EFFICIENCY (Filtration) _EN14683:2019+AC 2019:
Condições teste: Temperatura e Humidade relativa // Test conditions: Temperature and Relative humidity: 21±5ºC / 85± 5 %
Área de cada réplica/ Dimensions of the test specimens: 49cm2 (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 2.8
Valor médio da contagem total de 2 controles positivos/Average of the total quantification of 2 positive controls (CFU): 2136
Valor médio da contagem do controle negativo/Average of the quantification of the negative control (CFU): 12
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 (%)
99.1
99.1
99.0
99.0
99.1

DIFFERENCIAL PRESSURE (Breathability) _EN14683:2019+AC 2019:
Condições teste: Temperatura e Humidade relativa // Test conditions: Temperature and Relative humidity: 21±5ºC / 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)
30,6
31,6
29,6
28,6
28,6

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Lot:	MB001	**Expiration:**	---
Type:	Medical Device - Masks	**Size:**	Adult
Composition:	Polypropylene, black color		

ANALYSIS

Entry Date: 12/05/2021	**Period of analysis:** 12/05/2021 a 19/05/2021	**Ref. Sample:** 20217900

Description	Methods	Unit	Results/Uncertainty	Lim. lei	VMR

SPLASH RESISTANCE PRESSURE _ISO 22609:2004:
Condições teste: Amostra pré-condicionadas pelo menos 4horas a Temperatura e Humidade relativa de 21±5ºC / 85± 5 %// Test conditions: Samples pre-condictioned for at least 4 hoursat Temperature and Relative humidity: 21±5ºC / 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: 21.3 KPa) aimed at the centre of the mask.
Teste realizado à temperatura do laboratório de 21ºC e 45% humidade relativa, após 60 segundos da remoção da câmara de condionamento // Test performed at laboratory temperature of 21ºC 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 L202015 // Synthetic blood according to Annex B of ISO 22609: 2004 with surface tension of 42 + 2mN / m, batch L202015
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%, acording 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%, acording 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	--	Pass
Amost2	--	Pass
Amost3	--	Pass
Amost4	--	Pass
Amost5	--	Pass
Amost6	--	Pass
Amost7	--	Pass
Amost8	--	Pass
Amost9	--	Pass
Amost10	--	Pass
Amost11	--	Pass

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Description	Methods	Unit	Results/Uncertainty	Lim. lei	VMR
Amost12 -- Pass					
Amost13 -- Pass					
Amost14 -- Pass					
Amost15 -- Pass					
Amost16 -- Pass					
Amost17 -- Pass					
Amost18 -- Pass					
Amost19 -- Pass					
Amost20 -- Pass					
Amost21 -- Pass					
Amost22 -- Pass					
Amost23 -- Pass					
Amost24 -- Pass					
Amost25 -- Pass					
Amost26 -- Pass					
Amost27 -- Pass					
Amost28 -- Pass					
Amost29 -- Pass					
Amost30 -- Pass					
Amost31 -- Pass					
Amost32 -- Pass					

MICROBIAL CLEANLINESS (Bioburden) _ EN ISO 11737-1:2018:
5 min shaker at 250rpm
Área of each test specimen: 5 test specimens
Mic30ºC (3 days), Molds and yeasts 25ºC (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%
20
20
19
16
14

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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. Inspecão Visual/ Visual Inspection: - Ajuste do clipe nasal // Nasal clip adjustment - 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: Deutshes Institut fur 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 Deteção; 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 ≤ 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, 20 de maio de 2021

Laboratory Director

Maria Cristina Antão, Dra.

(This Test Report was digitally signed)

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