| | |
|---|---|
| **Analytical Report Nr.** | AR-20-YL-007362-01 |
| **Sample code Nr.** | 560-2020-00007819 |
| **Date** | 06/11/2020 |

# ANALYTICAL REPORT

## Client Information

Fergotex – Fábrica de Malhas Têxteis, Lda.
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Vila Nova de Famalicão PORTUGAL
+351 252910200
carlospereira@fergotex.pt
For the attention of Mr Carlos Pereira

## Sample Information

| | |
|---|---|
| **Order Code:** | EUAA70-00008926 |
| **Reception Date:** | 26-Oct-2020 |
| **Analysis Starting Date:** | 26-Oct-2020 |
| **Analysis Ending Date:** | 3-Nov-2020 |
| **Sample code Nr.** | 560-2020-00007819 |
| **Sample described as:** | Face mask |

## Requirements and decision rule

| | |
|---|---|
| **Customer requirements:** | CWA 17553:2020 Community face coverings requirements- Level 70% |
| **Decision Rule:** | Shared risk - Simple acceptance. |

## Information provided by the customer*

| | |
|---|---|
| **Client Reference:** | FRGMSK -01 |
| **Sample Description:** | Community mask CWA 17553 |
| **Purchase Order Number:** | |
| **Batch** | Not provided |

| | |
|---|---|
| **Analytical Report Nr.** | AR-20-YL-007362-01 |
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## SAMPLE PICTURE


**Eurofins Textile Testing Spain, S.L.U.**
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**Phone**+34 966 299 638
**www.eurofins.com/tex**

**Analytical Report Nr.** AR-20-YL-007362-01
**Sample code Nr.** 560-2020-00007819
**Date** 06/11/2020

**CONCLUSION:**

| TEST PROPERTY | PASS | FAIL | REMARKS |
|---|---|---|---|
| • **Bacterial Filtration Efficiency (BFE)** EN 14683:2019+AC:2019 Annex B | | | |
| A-Mask | X | | |
| **Breathability (Differential Pressure)** EN 14683:2019+AC:2019 Annex C | | | |
| A-Mask | X | | |
| **Resistance against penetration by synthetic blood** ISO 22609:2004 | | | |
| A-Mask | | | REFER RESULT |

**Remark:** Test has been performed as per application request

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**COMPONENT LIST:**

| COMPONENT ID | COMPONENT NAME | MATERIAL DESCRIPTION | COLOR | REMARKS |
|---|---|---|---|---|
| CUST 01 | A-Mask | Face mask | Blue | --- |

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| MASKS TESTING | CAS No. | RESULTS | UNC. | LOQ | GUIDELINES |
|---|---|---|---|---|---|

## Analyses on:A-Mask

### Resistance against penetration by synthetic blood

Analysis Ending Date: 03/11/2020

**ISO 22609:2004**

| | | | | | |
|---|---|---|---|---|---|
| Result: | | 3 of 32 samples pass at 16 kPa | | - | |

Complete test data reported at Annex.

AQL information according to ISO 22609:2004:
A single sampling plan providing an AQL of 4,0 % requires 32 test specimens.
An AQL of 4.0 % is met for a single sampling plan when 29 or more specimens show pass results.
AQL= Acceptable Quality Limit.

### Breathability (Differential Pressure)

Analysis Ending Date: 03/11/2020

**EN 14683:2019+AC:2019 Annex C**

| | | | | | |
|---|---|---|---|---|---|
| Differential pressure | 18.6 Pa/cm² | (± 1.0) Pa/cm² | - | <60 Pa/cm² | ✓ Pass |

Complete test data reported at Annex.

- **Bacterial Filtration Efficiency (BFE)**

Analysis Ending Date: 03/11/2020

**EN 14683:2019+AC:2019 Annex B**

| | | | | | |
|---|---|---|---|---|---|
| Bacterial Filtration Efficiency (BFE) | 83.52 % | | - | ≥ 70 % | ✓ Pass |

Complete test report attached as annex.
Test covered by ACCREDIA accreditation scope nº 1827 L

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| | |
|---|---|
| **Analytical Report Nr.** | AR-20-YL-007362-01 |
| **Sample code Nr.** | 560-2020-00007819 |
| **Date** | 06/11/2020 |

**Signed for and on behalf of Eurofins Textile Testing Spain:**

Report electronically validated by

**Luis Miralles Esteve**
Quality Manager

## EXPLANATORY NOTE

- ◆ Test not covered by ENAC accreditation scope
- ● Test is subcontracted within Eurofins group and is accredited
- ○ Test is subcontracted within Eurofins group and is not accredited
- ■ Test is subcontracted outside Eurofins group and is accredited
- □ Test is subcontracted outside Eurofins group and is not accredited

N/A = Not Applicable

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Test uncertainties not reported are at customer disposal, for those tests in which it is possible to evaluate the test uncertainty.
The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor k = 2, which for a normal distribution provides a level of confidence of approximately 95%.
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**End Of Report**

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## METHOD FOR DETERMINATION OF BREATHABILITY (DIFFERENTIAL PRESSURE)

Test Method: EN 14683: 2019+AC: 2019 Annex C

Number of test specimens: 5

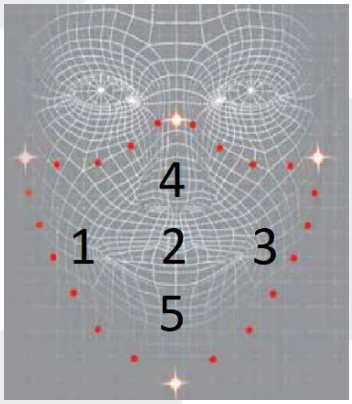
Number of test per specimen: 5

Sample area tested: Circular, diameter 2,5 cm

Tested area of the test sample: 4,9 $cm^2$

Flow rate during testing: 8±0,25 l/min

General location of measurement areas: Representative of the overall surface.




**Results**

| Specimen | Units (Pa) | | | | | | ΔP ($Pa/cm^2$) |
|---|---|---|---|---|---|---|---|
| | Position 1 | Position 2 | Position 3 | Position 4 | Position 5 | Mean value (Pa) | |
| 1 | 88 | 85 | 90 | 91 | 85 | 88 | 17,9 |
| 2 | 95 | 88 | 91 | 89 | 88 | 90 | 18,4 |
| 3 | 91 | 87 | 98 | 92 | 95 | 93 | 18,9 |
| 4 | 92 | 86 | 95 | 86 | 94 | 91 | 18,5 |
| 5 | 94 | 93 | 94 | 96 | 94 | 94 | 19,2 |
| | | | | | | **Mean Value** | **18,6** |
| | | | | | | **Uncertainty** | **± 1,0** |

**Observation:**

For thick and rigid masks the test method may not be suitable as a proper seal cannot be maintained in the sample holder.

## DETERMINATION RESISTANCE AGAINST PENETRATION BY SYNTETIC BLOOD

Test Method: ISO 22609:2004; Targeting-plate test method

Number of test specimens: 32

Sample size: Circular, diameter 5,58 cm

Sample area tested: 24,5 $cm^2$

Pressure: 16 kPa (120,0 mm Hg)

Stream velocity of synthetic blood: 550±10 cm/s

Distance of the face mask target area surface from the tip of the cannula: 30,5 cm

Angle of the pneumatic valve with respect to the face mask target area: 90º

Technique used to enhance visual detection of synthetic blood: Hydrophilic cotton

Conditioning: At least 4 hours. Tª between 16,7ºC and 26 ºC. HR% between 82,8 and 88 % Hr

Environmental test conditions 23,0 ºC; 84,2 % Hr

Pre-treatment: None

| Results | | |
|---|---|---|
| **Specimen** | **Pass** | **Fail** |
| 1 | | X |
| 2 | | X |
| 3 | | X |
| 4 | | X |
| 5 | | X |
| 6 | | X |
| 7 | | X |
| 8 | x | |
| 9 | | X |
| 10 | | X |
| 11 | | X |
| 12 | | X |
| 13 | | X |
| 14 | | X |
| 15 | | X |
| 16 | | X |
| 17 | | X |
| 18 | | X |
| 19 | x | |
| 20 | | X |
| 21 | | X |
| 22 | x | |
| 23 | | X |
| 24 | | X |
| 25 | | X |
| 26 | | X |
| 27 | | X |
| 28 | | X |
| 29 | | X |
| 30 | | X |
| 31 | | X |
| 32 | | X |

| **Conclusion** | **FAIL** |
|---|---|

**Operating requirements for surgical masks based on EN 14683: 2019+AC: 2019 standard**

| TEST | TYPE I | TYPE II | TYPE IIR |
|---|---|---|---|
| Bacterial filtration efficiency (BFE), (%) | ≥ 95 | ≥ 98 | ≥ 98 |
| Differential pressure (Pa/cm$^2$) | < 40 | < 40 | < 60 |
| Splash resistance pressure (kPa) | Not required | Not required | ≥ 16 |
| Microbial cleanliness (CFU/g) | ≤ 30 | ≤ 30 | ≤ 30 |

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ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO

**LAB N° 1827 L**



| | | | |
|---|---|---|---|
| **TEST REPORT** | Refer to Analytical Report Number | | |
| **SPONSOR** | Eurofins Textile & Footwear Testing Spain<br>C/Germán Bernácer 4<br>03203 Elche (Alicante)<br>SPAIN | | |
| **TEST METHOD** | Bacterial Filtration Efficiency (BFE) – EN 14683:2019+AC:2019 App B | | |
| **TEST ITEM - INFORMATION FROM THE SPONSOR** | | | |
| PRODUCT NAME | 560-2020-00007819 - Masks | | |
| MATRIX OF THE PRODUCT | Face Mask | | |
| BATCH | EUAA70-00008926 | CODE | Not provided |
| **EUROFINS COSMETICS & PERSONAL CARE ITALY IDENTIFICATION** | | | |
| MATERIAL ITEM ALIQUOT | N720AA0439-1 | | |
| PARCEL REGISTRATION N. | IP-N7-2020301-AAF | RECEIVING DATE | 27 Oct 2020 |
| **ANALYSIS STARTING DATE** | 28 Oct 2020 | **ANALYSIS ENDING DATE** | 29 Oct 2020 |
| **EXPERIMENTAL CONDITIONS** | Dimension of the test specimen: 175 mm x 100 mm<br>Size of the area tested: 49 $cm^2$<br>Flow rate during testing: 28,3 l/min<br>Inner side of the mask to the aerosol challenge. | | |
| **PHOTO OF THE TEST ITEM** |  | | |

**RESULTS**

| | RESULT | UNIT |
|---|---|---|
| ALIQUOT 1 | 83,54 | % |
| ALIQUOT 2 | 83,57 | % |
| ALIQUOT 3 | 82,61 | % |
| ALIQUOT 4 | 83,54 | % |
| ALIQUOT 5 | 84,33 | % |

| | |
|---|---|
| **DETAILED RESULTS** | See Addendum N. 1 *(1 page)* |



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ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO

**LAB N° 1827 L**



*Addendum N.1*

Started on: 28/10/2020

Batch: N720AA0439

Sample description: 560-2020-00007819 - Masks

Lot Number: EUAA70-00008926

**Negative Control Plate Counts**

| | Stage 1 | Stage 2 | Stage 3* | Stage 4* | Stage 5* | Stage 6* | Mean |
|---|---|---|---|---|---|---|---|
| Negative Control (CFU) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

*number of colonies adjusted with positive-hole correction table

**Positive Controls Plate Counts**

| | Stage 1 | Stage 2 | Stage 3* | Stage 4* | Stage 5* | Stage 6* | Total CFU |
|---|---|---|---|---|---|---|---|
| Size of particle (µm) | 7,00 | 4,70 | 3,30 | 2,10 | 1,10 | 0,65 | |
| Positive Control N.1 (CFU) | 203 | 342 | 1010 | 715 | 362 | 262 | 2894 |
| Positive Control N.2 (CFU) | 236 | 386 | 902 | 597 | 459 | 345 | 2925 |

*number of colonies adjusted with positive-hole correction table

Mean of the total plate counts of the two positive controls (CFU): 2910

**Mean Particle Size (MPS)**

| | MPS |
|---|---|
| Positive Control N.1 (µm) | 2,91 |
| Positive Control N.2 (µm) | 2,88 |
| Mean (µm) | 2,90 |

**Test specimens Plate Counts**

| | Stage 1 | Stage 2 | Stage 3* | Stage 4* | Stage 5* | Stage 6* | Total CFU |
|---|---|---|---|---|---|---|---|
| N720AA0439-1 - Aliquot 1 | 4 | 8 | 41 | 65 | 153 | 208 | 479 |
| N720AA0439-1 - Aliquot 2 | 3 | 6 | 31 | 67 | 163 | 208 | 478 |
| N720AA0439-1 - Aliquot 3 | 4 | 12 | 30 | 87 | 172 | 201 | 506 |
| N720AA0439-1 - Aliquot 4 | 6 | 9 | 38 | 63 | 154 | 209 | 479 |
| N720AA0439-1 - Aliquot 5 | 4 | 10 | 41 | 60 | 153 | 188 | 456 |

*number of colonies adjusted with positive-hole correction table

**Test specimens Bacterial Filtration Efficiency (BFE)**

| | BFE (%) |
|---|---|
| N720AA0439-1 - Aliquot 1 | 83,54 |
| N720AA0439-1 - Aliquot 2 | 83,57 |
| N720AA0439-1 - Aliquot 3 | 82,61 |
| N720AA0439-1 - Aliquot 4 | 83,54 |
| N720AA0439-1 - Aliquot 5 | 84,33 |

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Reviewed and electronically signed for Technical Supervisor Approval by
Martina Casini, Laboratory Manager
for Eurofins Cosmetic & Personal Care Italy Srl, on 29-Oct-2020 15:22:32 UTC+01:00