



# CERTIFICATE



**Management System as per  
EN ISO 13485 : 2016**

In accordance with TÜV AUSTRIA procedures, it is hereby certified that

**COMO P.C.**

**26th km Old Road Thessalonikis – Evzonon,  
GR570 11 THESSALONIKI, GREECE**

Applies a Quality Management System for Medical Devices in line with the above Standard for the following Scope

**MANUFACTURING AND DISTRIBUTION OF DISPOSAL MEDICAL MASKS.**

Certificate Registration No.: **20302200003971**

Valid until: 2023-11-04

Maria Agapitou  
Head of Management Systems & Products Certification Division  
Certification Body  
at TÜV AUSTRIA

Athens, 2020-11-05

This certification was conducted in accordance with TÜV AUSTRIA auditing and certification procedures and is subject to regular surveillance audits.

TÜV AUSTRIA HELLAS  
429, Mesogeion Ave.  
GR-153 43 Athens, Greece  
[www.tuvaustriahellas.gr](http://www.tuvaustriahellas.gr)



CePRK413\_ASe

Headquarters in Athens bear the responsibility of the Certification decision



# ΠΙΣΤΟΠΟΙΗΤΙΚΟ

**TÜV**  
AUSTRIA

Για το Σύστημα Διαχείρισης  
σύμφωνα με το Πρότυπο  
EN ISO 13485 : 2016

Τεκμηριώθηκε και βεβαιώνεται μέσω των Διαδικασιών της TÜV AUSTRIA, ότι η

**COMO I.K.E.**

**26° χλμ Παλαιάς οδού Θεσσαλονίκης – Ευζώνων  
570 11 ΘΕΣΣΑΛΟΝΙΚΗ, ΕΛΛΑΔΑ**

Εφαρμόζει ένα Σύστημα Διαχείρισης Ποιότητας για Ιατροτεχνολογικές Συσκευές και Προϊόντα σε συμφωνία με το παραπάνω Πρότυπο για το ακόλουθο Πεδίο Εφαρμογής

**ΠΑΡΑΓΩΓΗ ΚΑΙ ΕΜΠΟΡΙΑ ΙΑΤΡΙΚΩΝ ΜΑΣΚΩΝ ΜΙΑΣ ΧΡΗΣΗΣ.**

Αριθ. Εγγραφής Πιστοποιητικού: **20302200003971**

Ισχύει έως: 2023-11-04

Μαρία Αγαπητού  
Διευθύντρια Πιστοποίησης Συστημάτων Διαχείρισης και Προϊόντων

Οργανισμός Πιστοποίησης  
TÜV AUSTRIA

Αθήνα, 2020-11-05

Η παρούσα Πιστοποίηση πραγματοποιήθηκε σύμφωνα με την Διαδικασία Επιθεώρησης και Πιστοποίησης της TÜV AUSTRIA και επιτηρείται σε τακτά χρονικά διαστήματα.

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Headquarters in Athens bear the responsibility of the Certification decision

022532-18-4

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ZERTIFIKAT | CERTIFICATE | CERTIFICAT | CERTIFICADO | CERTIFIKAT | 証明書 | 证书 | 인증서






Cosmetics &  
Personal Care



LAB N° 1827 L

Page: 1 of 2

<b>TEST REPORT</b>	Refer to Analytical Report Number		
<b>SPONSOR</b>	COMO MONOPROSOPI KE		
	26KLM OLD NATIONAL ROAD		
	THESSALONIKIS EVZONON		
	GREECE		
<b>TEST METHOD</b>	Bacterial Filtration Efficiency (BFE) – EN 14683:2019+AC:2019 App B		
<b>TEST ITEM - INFORMATION FROM THE SPONSOR</b>			
PRODUCT NAME	Medical disposable face masks		
MATRIX OF THE PRODUCT	Face Mask		
BATCH	211020A	CODE	Not provided
<b>EUROFINS COSMETICS &amp; PERSONAL CARE ITALY IDENTIFICATION</b>			
MATERIAL ITEM ALIQUOT	N720AA0381-1		
PARCEL REGISTRATION N.	IP-N7-2020297-AAA	RECEIVING DATE	23 Oct 2020
ANALYSIS STARTING DATE	26 Oct 2020	ANALYSIS ENDING DATE	27 Oct 2020
<b>EXPERIMENTAL CONDITIONS</b>	Dimension of the test specimen: 170 mm x 95 mm Size of the area tested: 49 cm <sup>2</sup> Flow rate during testing: 28,3 l/min Inner side of the mask to the aerosol challenge.		
<b>PHOTO OF THE TEST ITEM</b>			
<b>RESULTS</b>			
		<b>RESULT</b>	<b>UNIT</b>
	ALIQUOT 1	98,17	%
	ALIQUOT 2	98,64	%
	ALIQUOT 3	98,67	%
	ALIQUOT 4	98,85	%
	ALIQUOT 5	98,53	%
<b>DETAILED RESULTS</b>	See Addendum N. 1 (1 page)		

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 The test results relate only to the tested items. Sampling, except specific indication on test report, is always intended to be made by the Sponsor.  
 Information on the test item provided by the Sponsor are under Sponsor responsibility.*

**Eurofins Cosmetics & Personal Care Italy Srl** – via B.Buozzi 2, Vimodrone (Milano), Italy –  
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Cosmetics &  
Personal Care



Started on: 26/10/2020

Batch: N720AA0381

Sample description: Medical disposable face masks

Lot Number: 211020A

#### 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)	220	308	785	477	311	217	2318
Positive Control N.2 (CFU)	247	292	1089	472	276	211	2587

\*number of colonies adjusted with positive-hole correction table

Mean of the total plate counts of the two positive controls (CFU): 2452

#### Mean Particle Size (MPS)

	MPS
Positive Control N.1 (µm)	2,98
Positive Control N.2 (µm)	3,11
Mean (µm)	3,05

#### Test specimens Plate Counts

	Stage 1	Stage 2	Stage 3*	Stage 4*	Stage 5*	Stage 6*	Total CFU
N720AA0381-1 - Aliquot 1	0	0	0	4	13	27	44
N720AA0381-1 - Aliquot 2	0	0	0	0	11	20	31
N720AA0381-1 - Aliquot 3	0	0	0	2	7	25	34
N720AA0381-1 - Aliquot 4	0	0	0	4	7	22	33
N720AA0381-1 - Aliquot 5	0	0	0	2	6	30	38

\*number of colonies adjusted with positive-hole correction table

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

	BFE (%)
N720AA0381-1 - Aliquot 1	98,17
N720AA0381-1 - Aliquot 2	98,64
N720AA0381-1 - Aliquot 3	98,67
N720AA0381-1 - Aliquot 4	98,85
N720AA0381-1 - Aliquot 5	98,53



**Analytical Report Nr.**

AR-20-YL-006895-01

**Sample code Nr.**

560-2020-00007809

**Date**

27/10/2020

**ANALYTICAL REPORT****Client Information**

Eurofins Cosmetics and Personal Care Italy Srl  
Lungotevere A. da Brescia, 11  
ROMA ITALY

StaffCOSME@eurofins.com

For the attention of Dept Reports &amp; Sample Registration

**Sample Information**

**Order Code:** EUAA70-00008920  
**Reception Date:** 26-Oct-2020  
**Analysis Starting Date:** 26-Oct-2020  
**Analysis Ending Date:** 27-Oct-2020  
**Sample code Nr.** 560-2020-00007809  
**Sample described as:** Masks

**Requirements and decision rule**

**Customer requirements:** No requirements  
**Decision Rule:** Not applicable.

**Information provided by the customer\***

**Client Reference:** MEDICAL DISPOSABLE FACS MASKS  
**Sample Description:** COMO MONOPROSOPI IKE  
**Purchase Order Number:**

**Batch** 211020A

**Analytical Report Nr.**

AR-20-YL-006895-01

**Sample code Nr.**

560-2020-00007809

**Date**

27/10/2020

**SAMPLE PICTURE**

**Analytical Report Nr.**

AR-20-YL-006895-01

**Sample code Nr.**

560-2020-00007809

**Date**

27/10/2020

**CONCLUSION:**

TEST PROPERTY	PASS	FAIL	REMARKS
<b>Breathability (Differential Pressure)</b> EN 14683:2019+AC:2019 Annex C			
A - Mask			REFER RESULT

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



**Analytical Report Nr.**

AR-20-YL-006895-01

**Sample code Nr.**

560-2020-00007809

**Date**

27/10/2020

**COMPONENT LIST:**

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

**Analytical Report Nr.**

AR-20-YL-006895-01

**Sample code Nr.**

560-2020-00007809

**Date**

27/10/2020

MASKS TESTING	CAS No.	RESULTS	UNC.	LOQ	GUIDELINES
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**Analyses on: A - Mask****Breathability (Differential Pressure)**

Analysis Ending Date: 27/10/2020

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

Differential pressure

25.3 Pa/cm<sup>2</sup>

-

Complete test data reported at Annex.

**Analytical Report Nr.**

AR-20-YL-006895-01

**Sample code Nr.**

560-2020-00007809

**Date**

27/10/2020

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

Report electronically validated by

**Axel Ferrando**

Physical-Mechanical Lab Manager

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**EXPLANATORY NOTE**

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- ◆ 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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\*Eurofins Textile Testing Spain S.L.U is not responsible of the information supplied by the costumer and reported as section "Information provided by the costumer\*".

Eurofins General Sales Terms and Conditions Applied.

Results obtained refer only to samples, products or material received in Laboratory, as described in section "Sample information" and tested in conditions shown in present report.

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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If you happen to have any comments, please do it by sending email to [textile\\_spain@eurofins.com](mailto:textile_spain@eurofins.com) and referring to this report number.

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**End Of Report**

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**Eurofins Textile Testing Spain, S.L.**

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SPAIN

**Phone**+34 966 299 638**www.eurofins.com/tex**

ENAC is signatory of EA and ILAC Multilateral Agreement for testing  
Activities not covered by ENAC accreditation are marked with ◆ ○ ● ■



## METHOD FOR DETERMINATION OF BREATHABILITY (DIFFERENTIAL PRESSURE)

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

Number of test specimens: 5

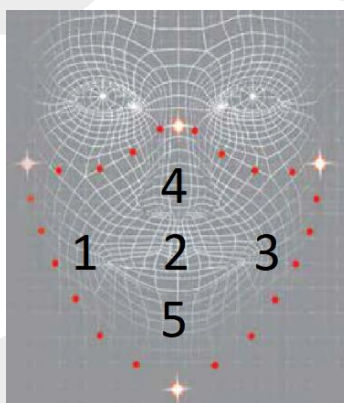
Number of test per specimen: 5

Sample area tested: Circular, diameter 2,5 cm

Tested area of the test sample: 4,9 cm<sup>2</sup>

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

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



## Results

Specimen	Units (Pa)						$\Delta P$ (Pa/cm <sup>2</sup> )
	Position 1	Position 2	Position 3	Position 4	Position 5	Mean value (Pa)	
1	116	127	129	126	125	125	25,4
2	122	114	123	127	123	122	24,9
3	123	118	127	131	125	125	25,5
4	121	126	123	129	125	125	25,5
5	122	129	124	125	120	124	25,3
						<b>Mean Value</b>	<b>25,3</b>
						<b>Uncertainty</b>	<b>± 1,3</b>

## Observation:

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

COMO MONOPROSOPI IKE  
26KLM OLD NATIONAL ROAD  
THESSALONIKIS EVZONON,  
GR

Client Account Number: A00925520THA  
Eurofins Quote Number: N3OPPT20006503

General Method Reference: EN 14683:2019/AC 2019 App D

Analysis	Specification	Result	Unit
<b>Eurofins Sample Number N720AA0384-1</b>			
MEDICAL DISPOSABLE FACE MASKS - aliquot 1; Lot # 211020A; Original Received Date 23-Oct-2020;			
<b>Microbial Cleanliness (Bioburden)</b>			
Aerobic count	----	18.81	CFU/g
Aerobic count	----	63.00	CFU/sample
Yeasts and Moulds	----	4.48	CFU/g
Yeasts and Moulds	----	15.00	CFU/sample
Total Bioburden	≤ 30	23.29	CFU/g
Total Bioburden	----	78.00	CFU/sample
Analysis Date: 23-Oct-2020 to 30-Oct-2020			

<b>Eurofins Sample Number N720AA0384-2</b>			
MEDICAL DISPOSABLE FACE MASKS - aliquot 2; Lot # 211020A; Original Received Date 23-Oct-2020;			
<b>Microbial Cleanliness (Bioburden)</b>			
Aerobic count	----	18.46	CFU/g
Aerobic count	----	65.00	CFU/sample
Yeasts and Moulds	----	11.22	CFU/g
Yeasts and Moulds	----	31.00	CFU/sample
Total Bioburden	≤ 30	25.29	CFU/g
Total Bioburden	----	85.00	CFU/sample
Analysis Date: 23-Oct-2020 to 30-Oct-2020			

<b>Eurofins Sample Number N720AA0384-3</b>			
MEDICAL DISPOSABLE FACE MASKS - aliquot 3; Lot # 211020A; Original Received Date 23-Oct-2020;			
<b>Microbial Cleanliness (Bioburden)</b>			
Aerobic count	----	15.88	CFU/g
Aerobic count	----	54.00	CFU/sample
Yeasts and Moulds	----	13.24	CFU/g
Yeasts and Moulds	----	45.00	CFU/sample
Total Bioburden	≤ 30	29.12	CFU/g
Total Bioburden	----	99.00	CFU/sample
Analysis Date: 23-Oct-2020 to 30-Oct-2020			

Analysis	Specification	Result	Unit
<b>Eurofins Sample Number N720AA0384-4</b>			
MEDICAL DISPOSABLE FACE MASKS - aliquot 4; Lot # 211020A; Original Received Date 23-Oct-2020;			
<b>Microbial Cleanliness (Bioburden)</b>			
Aerobic count	----	17.88	CFU/g
Aerobic count	----	59.00	CFU/sample
Yeasts and Moulds	----	10.22	CFU/g
Yeasts and Moulds	----	41.00	CFU/sample
Total Bioburden	≤ 30	27.94	CFU/g
Total Bioburden	----	92.00	CFU/sample
Analysis Date: 23-Oct-2020 to 30-Oct-2020			

<b>Eurofins Sample Number N720AA0384-5</b>			
MEDICAL DISPOSABLE FACE MASKS - aliquot 5; Lot # 211020A; Original Received Date 23-Oct-2020;			
<b>Microbial Cleanliness (Bioburden)</b>			
Aerobic count	----	17.72	CFU/g
Aerobic count	----	61.00	CFU/sample
Yeasts and Moulds	----	7.24	CFU/g
Yeasts and Moulds	----	15.00	CFU/sample
Total Bioburden	≤ 30	23.79	CFU/g
Total Bioburden	----	79.00	CFU/sample
Analysis Date: 23-Oct-2020 to 30-Oct-2020			

<b>Sample Compliance Assessment</b>			
The following Samples meet the requirement(s) for all listed test(s) where specifications were applied: N720AA0384-1, N720AA0384-2, N720AA0384-3, N720AA0384-4, N720AA0384-5			



**Contracted Company: Eurofins Cosmetic & Personal Care Italy (Vimodrone)**

via Bruno Buozzi, 2, Vimodrone (MI), IT-20055 Italy

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*Questions about this report should be directed to your project manager or the general email listed above.*