Analytical Report Nr. AR-21-YL-004483-01
Sample code Nr. 560-2021-00004175
Date 27/04/2021

ANALYTICAL REPORT

Client Information

Intelligent Medical Services Producers
Madaba Industrial Estate - Sector No. 4 Building No. 3
Madaba JORDAN
+962 7705 050 64
heba@anfasmedical.com
For the attention of Heba Erekat

Sample Information

Order Code: EUAA70-00011508
Reception Date: 15-Apr-2021
Analysis Starting Date: 15-Apr-2021
Analysis Ending Date: 27-Apr-2021
Sample code Nr. 560-2021-00004175
Sample described as: Masks

Requirements and decision rule

Customer requirements: EN 14683:2019+AC:2019 TYPE IIR
Decision Rule: Shared risk - Simple acceptance. Probability of False Acceptance <50%

Information provided by the customer*

Client Reference: IMS-FM-IIR
Sample Description:
Purchase Order Number:

Batch Not provided

Analytical Report Nr.	AR-21-YL-004483-01
Sample code Nr.	560-2021-00004175
Date	27/04/2021

SAMPLE PICTURE

Eurofins Textile Testing Spain, S.L.U.
Calle Germán Bernácer, 4
03203 Elche
SPAIN
Phone+34 966 299 638
www.eurofins.com/tex

Analytical Report Nr. AR-21-YL-004483-01
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CONCLUSION:

TEST PROPERTY	PASS	FAIL	REMARKS
● **Bacterial Filtration Efficiency (BFE)** EN 14683:2019+AC:2019 Annex B			
A	X		
● **Microbial cleanliness (bioburden)** EN ISO 11737-1:2018			
A	X		
Breathability (Differential Pressure) EN 14683:2019+AC:2019 Annex C			
A	X		
■ **Biocompatibility** EN ISO 10993-10:2013 / EN ISO 10993-5:2009			
A	X		

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	Blue	---

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MASKS TESTING	CAS No.	RESULTS	UNC.	LOQ	GUIDELINES

Analyses on:A

- **Microbial cleanliness (bioburden)** — Analysis Ending Date: 27/04/2021

EN ISO 11737-1:2018

Bioburden		<30 cfu/g		-	≤ 30 cfu/g ✓ PASS

Complete test data reported at Annex.
Test covered by ACCREDIA accreditation scope nº 1827 L

- **Bacterial Filtration Efficiency (BFE)** — Analysis Ending Date: 23/04/2021

EN 14683:2019+AC:2019 Annex B

Bacterial Filtration Efficiency (BFE)		99.79 %		-	≥ 98 % ✓ PASS

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

Breathability (Differential Pressure) — Analysis Ending Date: 22/04/2021

EN 14683:2019+AC:2019 Annex C

Differential pressure		46.4 Pa/cm²	(± 1.8) Pa/cm²	-	<60 Pa/cm² ✓ PASS

Complete test data reported at Annex.

- **Biocompatibility** — Analysis Ending Date: 27/04/2021

EN ISO 10993-10:2013 / EN ISO 10993-5:2009

Cytotoxicity		Not cytotoxic		-	Not cytotoxic ✓ PASS
Irritation and skin sensitization		Not irritative		-	Not irritative ✓ PASS

Complete test data reported at Annex.

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Date 27/04/2021

Signed for and on behalf of Eurofins Textile Testing Spain:

Report electronically validated by

Axel Ferrando
Physical-Mechanical Lab 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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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** and referring to this report number.

End Of Report

Eurofins Textile Testing Spain, S.L.U.
Calle Germán Bernácer, 4
03203 Elche
SPAIN
Phone+34 966 299 638
www.eurofins.com/tex

eurofins | Cosmetics & Personal Care

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO

LAB N° 1827 L

TEST REPORT	Refer to Analytical Report Number		
SPONSOR	Eurofins Textile & Footwear Testing Spain C/Germán Bernácer 4 03203 Elche (Alicante) SPAIN		
TEST METHOD	Microbial cleanliness (Bioburden) – EN 14683:2019/AC 2019 par. 5.2.5 + App D		
TEST ITEM - INFORMATION FROM THE SPONSOR			
PRODUCT NAME	560-2021-00004175 - Masks		
MATRIX OF THE PRODUCT	Face Mask - Entire Mask		
BATCH	EUAA70-00011508	CODE	Not provided
EUROFINS COSMETICS & PERSONAL CARE ITALY IDENTIFICATION			
MATERIAL ITEM ALIQUOT	N721AA01333-1		
PARCEL REGISTRATION N.	IP-N7-2021106-AAC	RECEIVING DATE	16 Apr 2021
ANALYSIS STARTING DATE	19 Apr 2021	**ANALYSIS ENDING DATE**	26 Apr 2021

PHOTO OF THE TEST ITEM

RESULTS

RESULTS	SPECIFICATION	AEROBIC COUNT	MYCOTIC COUNT	TOTAL BIOBURDEN	UNIT
ALIQUOT 1	/	3.00	< 3.00	6.00	CFU/sample
	≤ 30	1.00	< 1.00	2.00	CFU/g
ALIQUOT 2	/	15.00	< 3.00	18	CFU/sample
	≤ 30	5.58	< 1.12	6.70	CFU/g
ALIQUOT 3	/	< 3.00	< 3.00	< 6.00	CFU/sample
	≤ 30	< 1.02	< 1.02	< 2.04	CFU/g
ALIQUOT 4	/	< 3.00	< 3.00	< 6.00	CFU/sample
	≤ 30	< 1.02	< 1.02	< 2.04	CFU/g
ALIQUOT 5	/	< 3.00	3.00	6.00	CFU/sample
	≤ 30	< 1.03	1.03	2.06	CFU/g

Eurofins Cosmetics & Personal Care Italy Srl – via B.Buozzi 2, Vimodrone (Milano), Italy –
P.IVA / VAT Number: 05533561006
Tel: +39-022507151 – Fax: +39-0225071599 – E-mail: : InfoCosme@eurofins.com

Reviewed and electronically signed for Technical Supervisor Approval by
Martina Casini, Laboratory Manager
for Eurofins Cosmetic & Personal Care Italy Srl, on 26-Apr-2021 14:02:50 UTC+02:00

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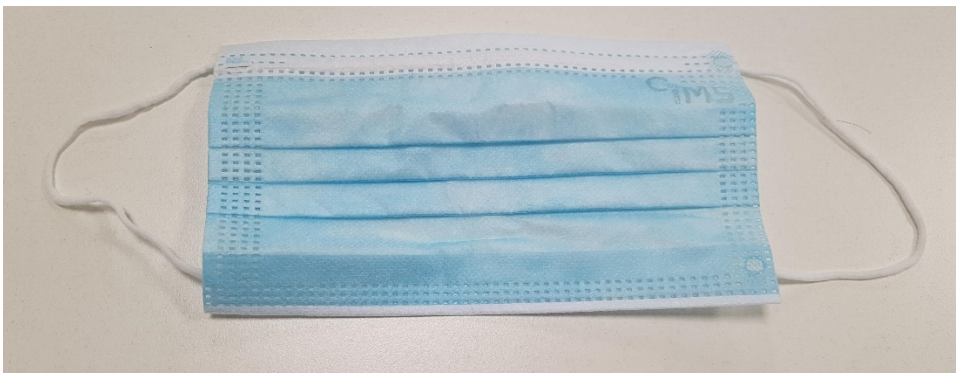
ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO

LAB N° 1827 L

TEST REPORT	Refer to Analytical Report Number		
SPONSOR	Eurofins Textile & Footwear Testing Spain C/Germán Bernácer 4 03203 Elche (Alicante) SPAIN		
TEST METHOD	Bacterial Filtration Efficiency (BFE) – EN 14683:2019+AC:2019 App B		
TEST ITEM - INFORMATION FROM THE SPONSOR			
PRODUCT NAME	560-2021-00004175 - Masks		
MATRIX OF THE PRODUCT	Face Mask – Entire Mask		
BATCH	EUAA70-00011508	CODE	Not provided
EUROFINS COSMETICS & PERSONAL CARE ITALY IDENTIFICATION			
MATERIAL ITEM ALIQUOT	N721AA1334-1		
PARCEL REGISTRATION N.	IP-N7-2021106-AAC	RECEIVING DATE	16 Apr 2021
ANALYSIS STARTING DATE	20 Apr 2021	**ANALYSIS ENDING DATE**	21 Apr 2021
EXPERIMENTAL CONDITIONS	Dimension of the test item: 175 mm x 95 mm Dimension of the test specimen (unfolded): 150 mm x 155 mm Size of the area tested: 49 cm^2 Flow rate during testing: 28,3 l/min Inner side of the mask to the aerosol challenge.		
PHOTO OF THE TEST ITEM			

RESULTS

	RESULT	UNIT
ALIQUOT 1	99,82	%
ALIQUOT 2	99,75	%
ALIQUOT 3	99,75	%
ALIQUOT 4	99,82	%
ALIQUOT 5	99,79	%

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

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P.IVA / VAT Number: 05533561006
Tel: +39-022507151 – Fax: +39-0225071599 – E-mail: : InfoCosme@eurofins.com

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LAB N° 1827 L

Addendum N.1

Started on: 20/04/2021

Batch: N721AA1334

Sample description: 560-2021-00004175 - Masks

Lot Number: EUAA70-00011508

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)	159	289	1036	659	335	204	2682
Positive Control N.2 (CFU)	180	350	1142	721	342	221	2956

*number of colonies adjusted with positive-hole correction table

Mean of the total plate counts of the two positive controls (CFU): 2819

Mean Particle Size (MPS)

	MPS
Positive Control N.1 (µm)	2,90
Positive Control N.2 (µm)	2,95
Mean (µm)	2,92

Test specimens Plate Counts

	Stage 1	Stage 2	Stage 3*	Stage 4*	Stage 5*	Stage 6*	Total CFU
N721AA1334-1 - Aliquot 1	0	0	0	0	2	3	5
N721AA1334-1 - Aliquot 2	0	0	0	0	1	6	7
N721AA1334-1 - Aliquot 3	0	0	0	0	2	5	7
N721AA1334-1 - Aliquot 4	0	0	0	0	2	3	5
N721AA1334-1 - Aliquot 5	0	0	0	0	2	4	6

*number of colonies adjusted with positive-hole correction table

Test specimens Bacterial Filtration Efficiency (BFE)

	BFE (%)
N721AA1334-1 - Aliquot 1	99,82
N721AA1334-1 - Aliquot 2	99,75
N721AA1334-1 - Aliquot 3	99,75
N721AA1334-1 - Aliquot 4	99,82
N721AA1334-1 - Aliquot 5	99,79

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P.IVA / VAT Number: 05533561006
Tel: +39-022507151 – Fax: +39-0225071599 – E-mail: : InfoCosme@eurofins.com

Reviewed and electronically signed for Technical Supervisor Approval by
Martina Casini, Laboratory Manager
for Eurofins Cosmetic & Personal Care Italy Srl, on 23-Apr-2021 11:53:48 UTC+02:00

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

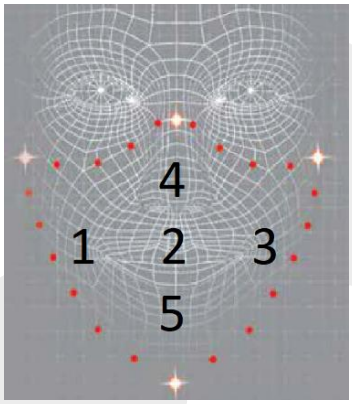
Tested area of the test sample: 4,9 cm^2

Flow rate during testing: 8±0,6 l/min

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

Conditioning: Tª between 16,7ºC and 26ºC. RH between 82,8% and 88% during at least 4 h.

Airflow direction during testing: From the inner layer to the outer layer.



Results

Specimen	Units (Pa)						ΔP (Pa/cm^2)
	Position 1	Position 2	Position 3	Position 4	Position 5	Mean value (Pa)	
1	249	239	200	223	211	224	45,8
2	199	224	231	228	207	218	44,4
3	239	227	231	229	246	234	47,8
4	231	239	250	248	252	244	49,8
5	214	240	219	199	206	216	44,0
						Mean Value	**46,4**
						Uncertainty	**± 1,8**

Observation:

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

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

Hauptsitz
Prüfinstitut
HygCen Austria GmbH
Werksgelände 28
Techno-Z / Bauteil 3
5500 Bischofshofen

Phone: +43 (0) 6462 5319
Fax: +43 (0) 6462 3275 3
Email: info@hygcen.at
Web: www.hygcen.at

[HYGCEN AUSTRIA GMBH | WERKSGELÄNDE 28 | 5500 BISCHOFSHOFEN]

Akkreditierte Prüfstelle nach ÖNORM EN ISO 17025

Intelligent Medical Services Producers

Madaba Industrial Estate - Sector No. 4

Building No. 3

Madaba

Jordan

Bischofshofen, 23.04.2021

Prüfbericht / *test report* B 27470

Labor-Nr. / *identification of the test laboratory:*	B 27470
Prüfprodukt / *test product*:	Mask - 560-2021-00004175 / EUAA70-00011508
Musterbezeichnung / *sample designation:*	IMS-FM-IIR
Chargen-Bez. / *batch number*:	n/a
Auftraggeber / *ordered by*:	Intelligent Medical Services Producers
Auftragsdatum / *date of order*:	2021-04-15
Materialeingang / *date of delivery*:	2021-04-19
Prüfzeitraum / *period of analysis*:	2021-04-21 bis / *to* 2021-04-23
Lagerbedingungen / *storage conditions*:	erfolgt nach Angabe des Herstellers / *according to the manufacturer´s specifications*
Prüfbedingungen / *test conditions:*	Die Prüfung erfolgte im Anlieferungszustand. / *The test was done in the delivery state.*
Prüfmethode / *test method*:	SOP 09-001 Biologische Beurteilung von Medizinprodukten Zytotoxizität von Eluaten gemäß / *Biological evaluation of medical devices testing according to* EN ISO 10993-5:2009 Teil 5: Prüfung auf Zytotoxizität, Anhang A, Aufnahme von Neutralrot / *Part 5: Tests for in vitro cytotoxicity, annex A, neutral red uptake (NRU)* Prüfung auf Irritation und Sensibilisierung gemäß / *Test for irritation and sensitization according to* EN ISO 10993-10:2013 Teil 10: Prüfung der Membranintegrität / *Part 10: Test of cell membrane integrity*

Probenbehandlung / *sample processing:*	gemäß / *according to* EN ISO 10993-12:2012 Das Produkt ist während des gesamten Prüfverfahrens aseptisch behandelt worden. / *The product was treated under aseptic conditions throughout the complete test procedure.*
Probenahme / *sampling:*	Es wurde ein repräsentatives Teil der Probe zur Überprüfung verwendet. / *A representative part of the test sample was used for testing.*
Raumtemperatur / *room temperature*:	22.4 °C
Relative Luftfeuchtigkeit (Raum) / *relative humidity (room)*:	27 %
Aussehen / *appaerance*:	Fotodokumentation im Anhang / *photo documentation in the annex*
Bestimmungsgemäße Anwendungsart gemäß Herstellerangaben / *Intended use according to the manufacturer*:	Medizinische Gesichtsmasken zur Verminderung der Infektionsverbreitung / *Medical face masks to minimise the risk of infection spreading.*

Extrakt / *extract*:

Extraktionsbedingungen / *conditions of extraction*:	gemäß / *according to* EN ISO 10993-12:2012
Extraktionsverhältnis / *extract ratio*:	6 cm²/ml
Extraktionsmenge und Volumen / *sample amount and volume*:	60 cm² Material in 10 ml Extraktionsmedium / *60 cm² material in 10 ml extraction medium*
Extraktionsmedium / *extraction medium*:	DMEM + 2% FBS + 1% Pen/Strep + L-Glutamin (Komplettmedium) / *DMEM supplemented with 2% FBS and 1% pen/strep + l-glutamine (complete medium)*
Extraktionsdauer / *duration of extraction*:	24 h ± 2h
Extraktionstemperatur / *temperature of extraction*:	37°C ± 1°C
pH-Wert des Extrakts / *pH value from the extract*:	B 27470 100% Extrakt / *extract* 8.32
Farbveränderung / *change of colour*	nein / *no*
Präzipitat / *precipitate*:	ohne / *without*
Extraktbehandlung / *treatment of extraction*:	keine / *none*
Extraktlagerung / *storage of extracts*:	nicht zutreffend / *not applicable*
Kommentare / *comments*:	keine / *none*

Beobachtungen Zellreaktion / *notice cell reaction*:	Morphologische Veränderungen / *morphological transformations*: nein / *no*

Prüfanforderung / *test requirement*:

EN ISO 10993-5, Anhang / *annex* A:	Neutralrot Methode / *neutral red uptake* Zellvitalität / *cell viability* ≥ 70%
EN ISO 10993-10:	LDHe Zellschädigung / cell damage ≤ 30%

Materialien und Methoden / *materials and methods*

Zellkultivierung / *cell culture:*	Vero-Zellen (ATCC CCL-81) sind eine adhärente Zelllinie des Nierengewebes einer äthiopischen Grünmeerkatze. Zur Testung wurden die Zellen in einer Konzentration von 1 x 10^5 Zellen/ml in 96-Well Mikrotiterplatten angelegt und 24 h bei 37°C und 5% CO_2 im Brutschrank inkubiert, um eine semikonfluente Einschichtkultur zu bilden. *Stock cultures of Vero cells (ATCC CCL-81), an adherent cell line derived from grivet kidney tissue, were used. Cells with a concentration of 1x10^5 cells/ml were seeded in 96-well microtitre plates and incubated 24 hours at 37°C and 5% CO_2 to form a cell culture monolayer.*
Exposition / *treatment:*	Nach 24 Stunden Inkubationszeit der Zellen wurde ein Mediumwechsel mit Testmedium vorgenommen. Dazu wurde das Medium dekantiert und 100 µl pro Vertiefung Prüfmedium hineinpipettiert. Eine Inkubation für 24 Stunden bei 37°C und 5% schließt sich an. *After 24 hours of incubation the medium was exchanged with the test medium by carefully decanting the medium and adding 100 µl of test medium, followed by incubation for an additional period of 24 hours at 37°C and 5% CO_2.*
Blindprobe NR Methode / *blank feed NR uptake:*	Als Blindprobe wurde Komplettmedium ohne Prüfmedium inkubiert. *As blank feed cells were incubated with complete medium without test medium.*
Extrakte / *extracts:*	Extrakte wurden frisch vor der Prüfung gemäß EN ISO 10993-12:2012 hergestellt, sofort für die Prüfung verwendet und nicht gelagert. *Extracts were generally prepared fresh according to EN ISO 10993-12:2012, used immediately for the assay and were not stored.*

Prüfmedium / *test medium:*	Das Prüfmedium ist der Extrakt (100%) oder eine Verdünnung davon, welche mit Komplettmedium hergestellt wurde. *The test medium is either the neat extract (100%) or a dilution of it, prepared with complete cell culture medium.*
NR Methode / *NR uptake:*	Vitale Zellen nehmen den Farbstoff Neutralrot auf. Tote Zellen können den Farbstoff nicht aufnehmen und bleiben ungefärbt. Die Farbintensität der Eluationslösung wurde photometrisch bei 540nm gemessen. *Viable cells incorporate the dye neutral red. Dead cells do not incorporate the dye and remain unstained.The intensity of the colour of the eluation solution was measured by using photometric determination at 540nm.*
LDHe Methode / LDHe method:	Lactatdehydrogenase (LDH), ein stabiles zytoplasmatisches Enzym, ist in allen Zellen präsent und wird bei Schädigung der Zellmembran oder Zell-Lyse in das Zellmedium freigesetzt. LDH reduziert Pyruvat zu Lactat, indem NADH zu NAD+ oxidiert wird. Die Umwandlung von NADH wird durch eine katalytisch gekoppelte gleichzeitige Umwandlung von INT zu einem unlöslichen Formazansalz photometrisch bestimmt. *Lactate dehydrogenase (LDH), a stable cytoplasmic enzyme, is present in the cytosol, but released into the medium if the cell membrane is damaged or the cells lyse. LDH reduces pyruvate to lactate in the presence of NADH, which is reduced to NAD+. Photometric detection follows the consumption of NADH using a catalytically coupled concomitant conversion of INT to an insoluble formazan salt as measurement endpoint*
Referenzkontrolle NR Methode / *reference control NR method:*	Als Negativkontrolle wurde sterile Baumwolle in Komplettmedium verwendet. Zusätzlich wurde als Positivkontrolle 0,15mg/ml Natriumdodecylsulfat im Test eingesetzt. *As negative control, cells were incubated with sterile cotton in complete medium. As positive control, cells were incubated in complete medium containing 0.15 mg/ml sodium dodecyl sulfate.*
Kontrollen LDH Methode / *controls LDH method:*	Als Negativkontrolle wurde Zellmedium ohne Prüflösung inkubiert. Zur Überprüfung der maximalen LDH-Freisetzung wurde zusätzlich als Positivkontrolle Triton X eingesetzt. *As negative control cells were treated with complete culture medium. The positive control for LDHe is Triton X, which results in maximal release of LDH from cells.*

Neutral Rot Ergebnisauswertung / *neutral red result evaluation:*	Die optische Dichte (A_{540}) von 12 Parallelansätzen wird ermittelt. Eine Zellvitalität von weniger als 70% bezogen auf die Blindprobe gilt als zytotoxisches Ergebnis. *Optical density (A_{540}) of 12 wells was determined. A cell viability of less than 70% relative to the blank feed is considered to be a cytotoxic result.*
LDHe Ergebnisauswertung / LDHe evaluation:	Die LDH-Freisetzung von 6 Parallelansätzen wurde ermittelt und relativ zur Positivkontrolle berechnet. Eine LDH-Freisetzung von >30% der Positivkontrolle zeigt eine signifikante Schädigung der Zellmembranen an. *LDH release of 6 wells was determined and calculated relative to the positive control. A LDH-release of >30% of the positive control shows a statistical significant damage of the cell membranes.*
NR-Medium / *NRmedium:*	NR-Farbstoff, Wasser, DMEM / *NR- dye, water, DMEM*
NR-Desorptionslösung / *desorption solution*:	Ethanol-/Eisessig Lösung / *ethanol-/ glacial acetic acid solution*

Zellen / *cells*:	CCLV Nr. / *No.*:	Charge / *batch*:	Passage / *passage*:	Firma / *company*:
	RIE 15	LOT 2708	P214	Friedrich-Loefler-Institut

	Charge / *batch*:	Ablaufdatum / *expiration date*:	Firma / *company*:
DMEM:	0000951330	2022-11-25	Lonza
Serum / *serum:*	BCCC8749	2024/12	Sigma-Aldrich
Antibiotika / *antibiotics*:	MS00P0	2022-04-19	biowest

Komplettmedium / *complete medium:* Herstellungsdatum / *date of production:* 2021-04-15

Abkürzungen / *abbreviations*

DMEM	Dulbecco's Modified Eagle's Medium	*Dulbecco's Modified Eagle's Medium*
FBS	Fetales Kälberserum	*Fetal Bovine Serum*
Pen/Strep	Penicillin, Streptomycin Antibiotialösung	*Penicillin, Streptomycin antibiotic solution*
ATCC	American Type Culture Collection	*The American Type Culture Collection*
NR	Neutralrot	*Neutral red*
ml	Milliliter	*Millilitre*
µl	Mikroliter	*Microliter*
Optische Dichte (A)	Absorption (A)	*Absorbance (A)*

Ergebnisauswertung Neutralrot Methode / *result neutral red uptake*:

Abbildung 1 / *Figure 1*: Boxplot der Zellvitalität / *Boxplot of the cell viability* B 27470

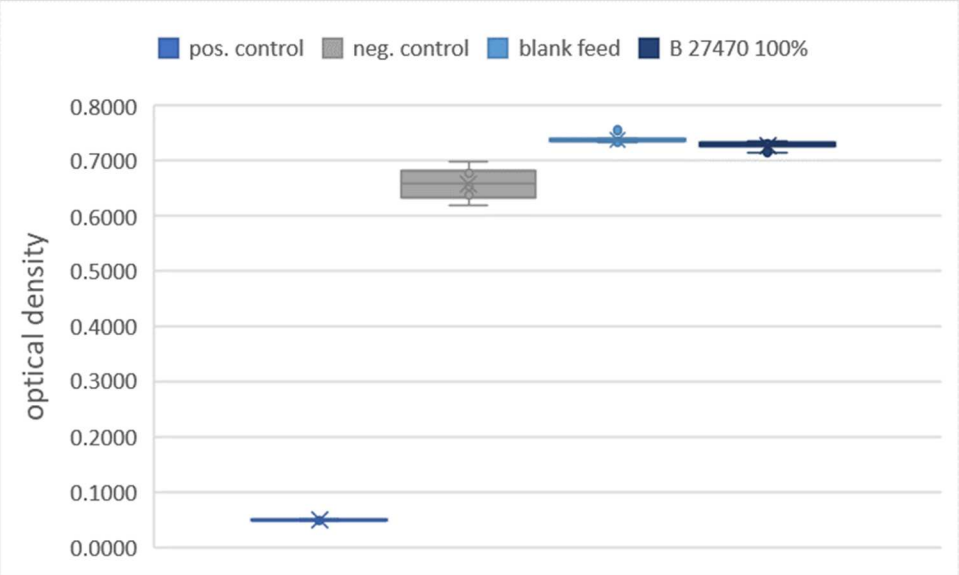


Tabelle 1 / *Table 1*: Deskriptive Statistik / *Descriptive statistics* B 27470

	N	Durch-schnitt / *mean*	Zellvitalität / *cell viability* (%)	Minimum	Maximum	Standard-abweichung / *standard deviation*	p-value[1]
Blind-probe / *blank feed*	9	0.738	100.00	0.733	0.755	0.007	-
Neg. Kontrolle / *neg. control*	6	0.658	89.17	0.619	0.698	0.028	-
Pos. Kontrolle / *pos. control*	9	0.049	6.65	0.048	0.051	0.001	-
B 27470 100%	12	0.728	98.59	0.714	0.736	0.007	0.887

Ergebnis / *result* B 27470:

98.59% Zellvitalität in Bezug auf die Blindprobe bei 100% Extrakt /
cell viability regarding to the blank feed using the 100% extract solution.

Verifizierung des Verfahrens
OD der Blindprobe ≥ 0,3
Eine Prüfung erfüllt die Annahmekriterien, wenn der linke und der rechte Mittelwert der Blindproben um nicht mehr als 15% vom Mittelwert aller Blindproben abweichen.
Verification of the process:
OD of blind value ≥ 0.3
Test was considered as positive when the difference of the mean values of the blank feeds on the left and on the right side of the plate do not deviate more than± 15% from all blank feeds together.

[1] U-Test nach Mann-Whitney vs. Kontrolle / *U test (Mann-Whitney) vs. Control*

Ergebnisauswertung LDH Methode / *result LDH method*:

Abbildung 2 / *Figure 2*: Freisetzung / *release* B 27470

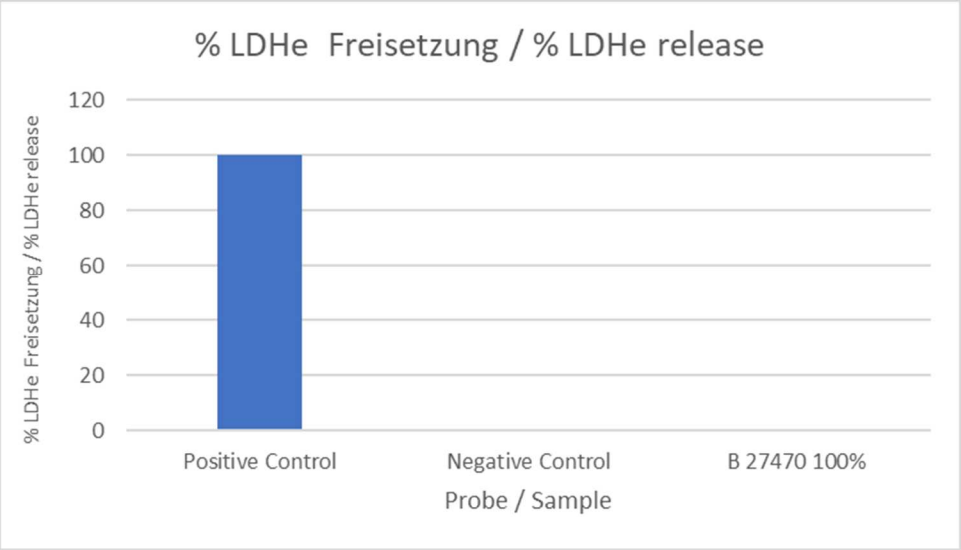


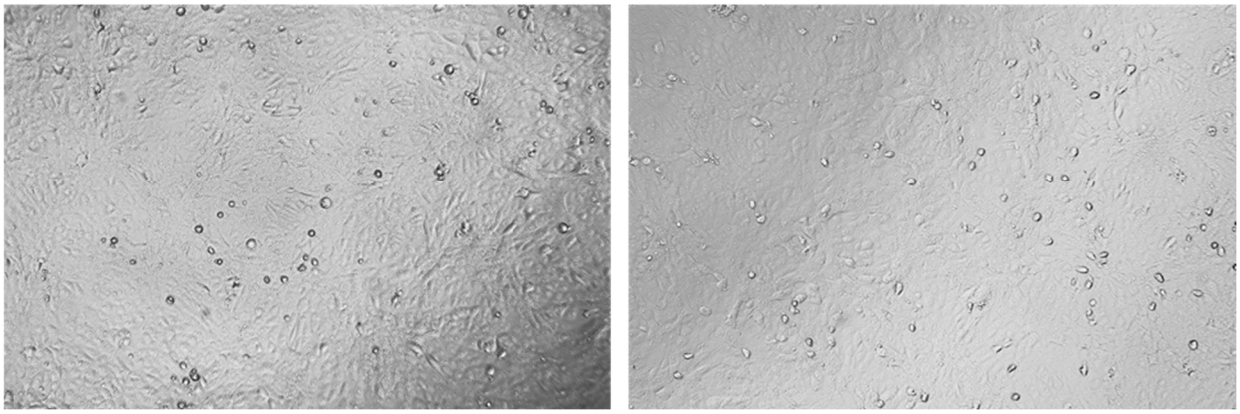
Tabelle 2 / *Table 2*: Deskriptive Statistik *Descriptive statistics* B 27470

	N	Standardabweichung / *standard deviation*	LDH Freisetzung / *LDH release* (%)
Pos. Kontrolle / *pos. control*	6	0.03	100
Neg. Kontrolle / *neg. control*	6	0.01	0.00
B 27470 100%	6	0.00	0.53

Qualitative morphologiebezogene Gradeinteilung der Zytotoxizität von Extrakten / *qualitative scale of cytotoxicity from extracts according to morphological changes*

Gradeinteilung / *scale*	Reaktivität / *reactivity*	Zustand der Kultur / *stauts of the culture*	27470
0	Keine / *none*	Diskrete intrazytoplasmatische Granuli, keine Zellauflösung, keine Verringerung des Zellwachstums / *discrete intracytoplasmic granuli, no cell lysis, no reduction of cell growth*	✓
1	Gering / *low*	Nicht mehr als 20% der Zellen sind rund, lose anhaftend und ohne intrazytoplasmatische Granuli oder zeigen Änderungen in der Morphologie, vereinzelt sind aufgelöste Zellen vorhanden, nur geringe Wachstumshemmung bemerkbar / *no more than 20% of the cells are round, loose adherent and without intracytoplasmic granuli or show morphological changes, rarely dissolved cells, slight growth inhibition detectable*	
2	Leicht / *mild*	Nicht mehr als 50% der Zellen sind rund, frei von intrazytoplasmatischen Granuli, keine ausgedehnte Zellauflösung; nicht mehr als 50% Wachstumshemmung bemerkbar / *no more than 50% of the cells are round, free of intracytoplasmic granuli, no extended cell lysis; no more than 50% growth inhibition detectable*	
3	Mäßig / *moderate*	Nicht mehr als 70% der Zellschichten enthalten runde Zellen oder sind aufgelöst; Zellschichten sind nicht vollständig zerstört, jedoch ist mehr als 50% Wachstumshemmung bemerkbar / *no more than 70% of the cells are round or dissolved; cell layers are not completly destroyed, but more than 50% growth inhibition is detectable*	
4	Stark / *strong*	Fast vollständige oder vollständige Zerstörung der Zellschichten / *almost complete or complete destruction of cell layers*	

Blindprobe / blank feed vs. B 27470



Schlussfolgerung / ***conclusion*:**

Bei 100% Extrakt des Produktes **Mask - 560-2021-00004175** / **EUAA70-00011508** resultierte eine Zellvitalität von mehr als 70% im Vergleich zur Blindprobe und ist deshalb **nicht** als **zytotoxisch** zu bewerten.

*The extract of 100% the product **Mask - 560-2021-00004175** / **EUAA70-00011508** resulted in a cell viability of more than 70% in comparison to the blank feed and can therefore be considered **not** as **cytotoxic**.*

Der Extrakt des Produktes **Mask - 560-2021-00004175** / **EUAA70-00011508** resultierte in einer LDH-Freisetzung von weniger als 30% im Vergleich zur Kontrolle und ist deshalb **nicht** als **irritativ** zu bewerten.

*The extract of the product **Mask - 560-2021-00004175** / **EUAA70-00011508** resulted in a LDH release less than 30% in comparison to the control and is therefore considered **not** to be **irritative**.*

Archivierung / *Archiving:*

Eine Ausfertigung des Berichtes wird zusammen mit den Rohdaten im Archiv der HygCen Austria GmbH aufbewahrt. / *A copy of this report is kept together with the raw data in the archive of HygCen Austria GmbH.*

Hinweis / *Note*:

Der vorliegende Prüfbericht bezieht sich ausschließlich auf die dem Labor vorliegenden Prüfgegenstände. Jede auszugsweise Vervielfältigung bedarf der schriftlichen Genehmigung durch die HygCen Austria GmbH. / *The present test report refers exclusively to the test objects available to the laboratory. Any duplication in extracts requires the written permission of HygCen Austria GmbH.*

Prof. Dr. med. H.-P. Werner
Technischer Leiter / *technical manager*

Monika Feltgen
Stellvertretender technischer Leiter / *vice technical manager*

Anhang zum Prüfbericht B 27470
attachment to test report B 27470

Abb. 1: Mask - 560-2021-00004175 / EUAA70-00011508

Analytical Report Nr. AR-21-YL-003278-01
Sample code Nr. 560-2021-00003363
Date 31/03/2021

ANALYTICAL REPORT

Client Information

Intelligent Medical Services Producers
Madaba Industrial Estate - Sector No. 4 Building No. 3
Madaba JORDAN
+962 7705 050 64
heba@anfasmedical.com
For the attention of Heba Erekat

Sample Information

Order Code: EUAA70-00011295
Reception Date: 29-Mar-2021
Analysis Starting Date: 29-Mar-2021
Analysis Ending Date: 31-Mar-2021
Sample code Nr. 560-2021-00003363
Sample described as: Masks

Requirements and decision rule

Customer requirements: EN 14683:2019+AC:2019 TYPE IIR
Decision Rule: Shared risk - Simple acceptance. Probability of False Acceptance <50%

Information provided by the customer*

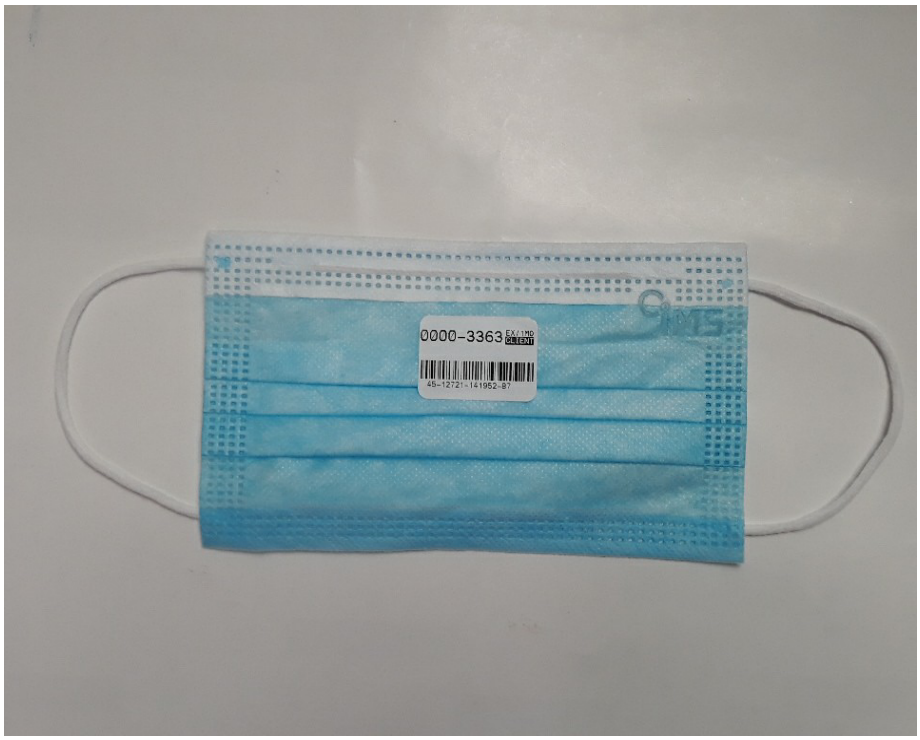
Client Reference: IMS-FM-01
Sample Description:
Purchase Order Number:

Batch 20032021ATIB

Eurofins Textile Testing Spain, S.L.U.
Calle Germán Bernácer, 4
03203 Elche
SPAIN
Phone+34 966 299 638
www.eurofins.com/tex

Analytical Report Nr.	AR-21-YL-003278-01
Sample code Nr.	560-2021-00003363
Date	31/03/2021

SAMPLE PICTURE



Eurofins Textile Testing Spain, S.L.U.
Calle Germán Bernácer, 4
03203 Elche
SPAIN
Phone+34 966 299 638
www.eurofins.com/tex

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CONCLUSION:

TEST PROPERTY	PASS	FAIL	REMARKS
Resistance against penetration by synthetic blood ISO 22609:2004			
Mask	X		

Remark: Test has been performed as per application request

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Sample code Nr. 560-2021-00003363
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COMPONENT LIST:

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

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Sample code Nr. 560-2021-00003363
Date 31/03/2021

MASKS TESTING	CAS No.	RESULTS	UNC.	LOQ		GUIDELINES
Analyses on:Mask						
Resistance against penetration by synthetic blood						Analysis Ending Date: 31/03/2021
ISO 22609:2004						
Number of specimens tested		32		-		
Number of specimens failed		1		-		
Number of specimens passed		31		-	≥29	✓ PASS

At least 29 of 32 specimens must pass tested at 16KPa

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.

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Signed for and on behalf of Eurofins Textile Testing Spain:

Report electronically validated by

Maria Jesus Martinez Puig
Chemical Lab 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

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%.

If you happen to have any comments, please do it by sending email to **textile_spain@eurofins.com** and referring to this report number.

End Of Report

Eurofins Textile Testing Spain, S.L.U.
Calle Germán Bernácer, 4
03203 Elche
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 ◆○●□■

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)

Synthetic blood volume: 2 ml

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 26ºC. RH between 82,8% and 88%

Environmental test conditions 17,9ºC; 83,5% Hr

Pre-treatment: None

Results		
Specimen	**Pass**	**Fail**
1	X	
2	X	
3	X	
4	X	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	**PASS**

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