dmcmask

www.dmcmask.com

MADE IN EUROPE

MEDICAL FACE MASK DM-101

CE TYPE IIR EN 14683: 2019 + AC 2019

FOR PROFESSIONAL USE

Tested by: eurofins

3-layer filtration

Microparticles Absorption

Safety & Health

Skin friendly fabric

Bacterial Filtration Efficiency > 98%

Available in three options: 5, 10 and 50 pcs. per pack

All our materials, products and manufacturing supervision are certified and fully comply with all EU and ISO standards and requirements.

eurofins

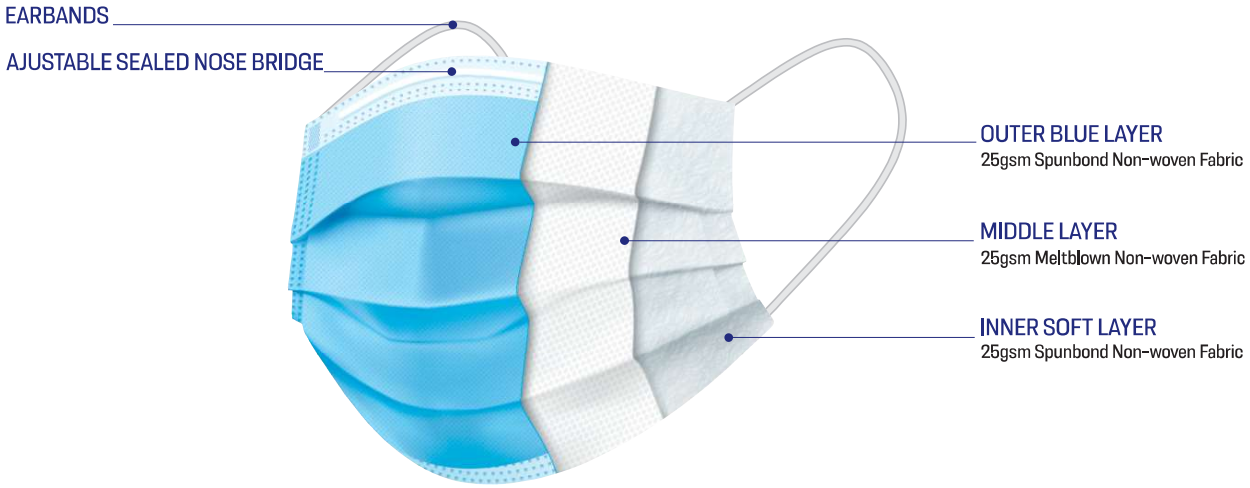
CE

TECHNICAL DATA SHEET

dmc mask

DMC MASK, DM-101 Disposable MEDICAL Face Mask (V2.0)

A 3ply face mask is a loose-fitting, disposable device that creates a physical barrier between the mouth and nose of a 3ply face mask is a loosefitting, disposable device that creates a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment.



MANUFACTURER:		Techdentika Tilzes st. 86, Siauliai, Lithuania
PRODUCT:		**MEDICAL FACE MASK**
PRODUCT NAME:		**DMC MASK**
CLASSIFICATION:		**Type IIR**
MODEL:		**DM-101** (Disposable 3-ply Medical Non Sterile Face Mask)
QUALITY ASSURANCE AND CONFORMITY:		**Directive 93/42/EEC**
	Regulation:	**(EU) 2017/745** of the European Parliament and of the Council of 5 April 2017 on Medical Devices **EN 14683:2019+AC:2019 Annex B** Bacterial Filtration Efficiency (BFE) **EN 14683:2019+AC:2019 Annex C** Brethability (Differential Pressure) **ISO 22609:2004** Resistance against penetration by synthetic blood **EN ISO 11737-1: 2018** Microbial cleanliness (Bioburden)
	Test reports:	AR-20-YL-005526-01 EUROFINS AR-20-YL-008082-01 EUROFINS
MATERIALS:	Outer Material	1st layer - 25mgs Spunbond Non-Woven
	Filter Layer	2nd layer - 25mgs Melt-Blown fabric
	Inner Material	3rd layer - 25mgs Spunbond Non-Woven
	Nose-piece	Plastic single wire thread 3mm
	Earloops	3mm Polyester and Spandex
SIZE:	Mask body	175x95mm (+/-5mm)
SHELF LIFE:		3 years after production date
STORAGE:		Storage under cool, clean and dry conditions. Avoid excessive heat (-20°C to +40°C and at less than 80% relative humidity)

EC Declaration of Conformity according to the EU Directive (CE)

EU Declaration of Conformity

Techdentika declares that this medical device complies with the following regulations:

MANUFACTURER:	**TECHDENTIKA, UAB** Tilzes st, 86, Siauliai, Lithuania
MEDICAL DEVICE:	**MEDICAL DISPOSABLE NON STERILE FACE MASK**
MEDICAL DEVICE BRAND NAME:	**DMC MASK**
MODEL:	**DM-101**
CLASSIFICATION:	**CLASS 1**
PRODUCT DESCRIPTION:	Medical device covering the mouth and nose providing a barrier to minimize the direct transmission of infective agents between staff and patient. This intended purpose is normally to limit the transmission of infective agents from staff to patients during surgical procedures and other medical settings with similar requirements. A medical face mask with an appropriate microbial barrier should also be effective in reducing the emission of infective agents from the nose and mouth of an asymptomatic carrier or a patient with clinical symptoms.

QUALITY ASSURANCE AND CONFORMITY:

Directive:	**Medical Device Directive 93/42/EEC**
Standard:	**EN 14683:2019+AC:2019**
Type:	**IIR**
Test report:	**AR-20-YL-00526-01 EUROFINS** **AR-20-YL-008082-01 EUROFINS**

This is hereby declared that following designated medical device complied with the essential requirements of above Council Directive(s) and standards.

Signed on behalf of **TECHDENTIKA**

LIETUVOS RESPUBLIKA REPUBLIC OF LITHUANIA UAB TECHDENTIKA LTD. VILNIUS

VILNIUS, LITHUANIA
Date: 2020/11/30
General manager VYTAUTAS ADOMAITIS

CE

Any issued Declarations on these products before 2020/11/30 are cancelled.
Document valid until 2021/11/30.

Analytical Report Nr. AR-20-YL-005526-01
Sample code Nr. 560-2020-00005729
Date 17/09/2020

ANALYTICAL REPORT

Client Information

UAB TECHDENTIKA
Savanoriu Avenue 178F
Vilnius LITUANIA
+37066677444
info@techdentika.lt
For the attention of Darjus Jancis

Sample Information

Order Code:	EUAA70-00007976
Reception Date:	31-Aug-2020
Analysis Starting Date:	31-Aug-2020
Analysis Ending Date:	17-Sep-2020
Sample described as:	Masks

Information provided by the customer:

Client Reference:	DM 101
Sample Description:	Manufacturer:Techdentika Brand: DMC Mask Model: DM101
Customer requirements:	No requirements
Purchase Order Number:	

Decision rule Not applicable. **Batch** Not provided

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

Analytical Report Nr. AR-20-YL-005526-01
Sample code Nr. 560-2020-00005729
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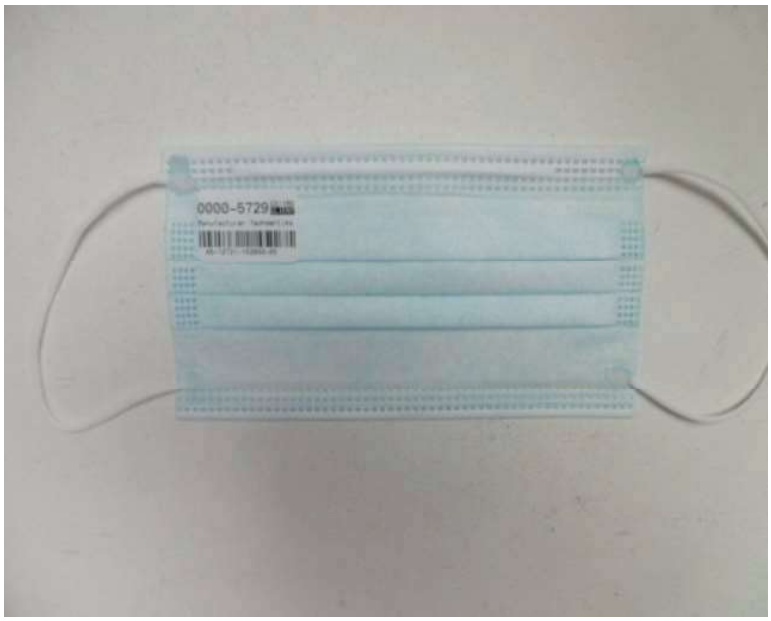
SAMPLE PICTURE



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Test report Annex
Analytical Report Nr. AR-20-YL-008082-01
Sample code Nr. 560-2020-00008989

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 21,6 ºC; 80,2 % 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	**PASS**

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Test report Annex
Analytical Report Nr. AR-20-YL-005526-01
Sample code Nr. 560-2020-00005729

METHOD FOR DETERMINATION OF BRETHABILITY (DIFFERENTIAL PRESSURE)

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

Number of test specimens: 5

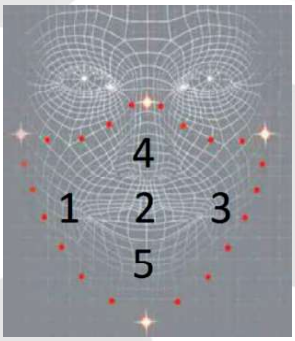
Number of test per specimen: 5

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	275	270	272	341	264	284	58,0
2	278	275	268	280	284	277	56,5
3	289	246	269	285	271	272	55,5
4	278	306	228	262	237	262	53,5
5	267	277	279	334	225	276	56,4
						Mean Value	**56,0**
						Uncertainty	**± 2,6**

Observation:

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

Test report Annex
Analytical Report Nr. AR-20-YL-005526-01
Sample code Nr. 560-2020-00005729

MICROBIAL CLEANLINESS (BIOBURDEN)

Test Method: EN ISO 11737-1: 2018

Number of test specimens: 5 of the same batch/lot

Results

	Biological Load Estimation			
	Ger. Aerob. Mesophiles 31ºC	Anaerobic bacteria	Molds and yeasts	Total
Test unit	CFU/g	CFU/g	CFU/g	CFU/g
1	20	5	10	35
2	16	14	8	38
3	17	0	11	28
4	19	0	3	22
5	20	0	1	21
			Average	**29**

Observation:

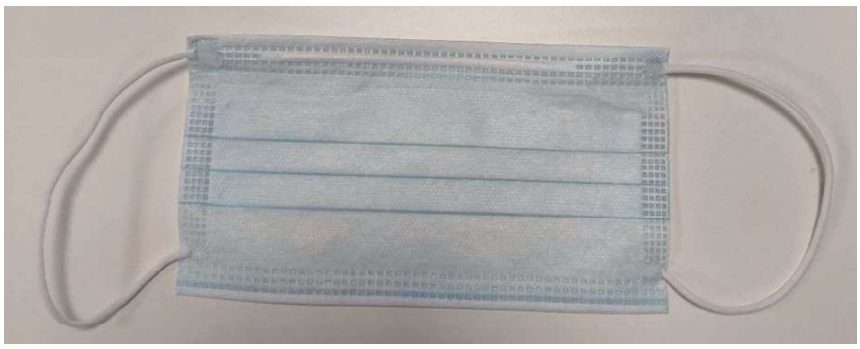
For Microbiology parameters, according to ISO 8199, re-counts between 1 and 3 CFUs represent a detection of the microorganism; and those between 4 and 9 CFUs are an estimated number.

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

Analytical Report: AAJ91264, Eurofins Number: LV20AB4066-5, Version: 1

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	560-2020-00005729		
MATRIX OF THE PRODUCT	Face Mask		
BATCH	EUAA70-00007976	CODE	Not provided
EUROFINS COSMETICS & PERSONAL CARE ITALY IDENTIFICATION			
MATERIAL ITEM ALIQUOT	LV20AB4066-5		
PARCEL REGISTRATION N.	IP-LV-2020246-AFG	RECEIVING DATE	02 Sep 2020
ANALYSIS STARTING DATE	09 Sep 2020	**ANALYSIS ENDING DATE**	16 Sep 2020
EXPERIMENTAL CONDITIONS	Dimension of the test specimen: 175 mm x 95 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	99,86	%
ALIQUOT 2	99,86	%
ALIQUOT 3	99,86	%
ALIQUOT 4	99,81	%
ALIQUOT 5	99,76	%

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

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Tel: +39-022507151 – Fax: +39-0225071599 – E-mail: : InfoCosme@eurofins.com

Addendum N.1

Started on: 09/09/2020

Batch: LV20AB4066

Sample description: 560-2020-00005729

Lot Number: EUAA70-00007976

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)	93	261	832	279	236	216	1917
Positive Control N.2 (CFU)	139	230	974	508	245	177	2273

*number of colonies adjusted with positive-hole correction table

Mean of the total plate counts of the two positive controls (CFU): 2095

Mean Particle Size (MPS)

	MPS
Positive Control N.1 (µm)	2,93
Positive Control N.2 (µm)	2,96
Mean (µm)	2,94

Test specimens Plate Counts

	Stage 1	Stage 2	Stage 3*	Stage 4*	Stage 5*	Stage 6*	Total CFU
LV20AB4066-5 - Aliquot 1	0	0	0	0	0	3	3
LV20AB4066-5 - Aliquot 2	0	0	0	0	1	2	3
LV20AB4066-5 - Aliquot 3	0	0	0	0	1	2	3
LV20AB4066-5 - Aliquot 4	0	0	0	0	1	3	4
LV20AB4066-5 - Aliquot 5	0	0	0	0	1	4	5

*number of colonies adjusted with positive-hole correction table

Test specimens Bacterial Filtration Efficiency (BFE)

	BFE (%)
LV20AB4066-5 - Aliquot 1	99,86
LV20AB4066-5 - Aliquot 2	99,86
LV20AB4066-5 - Aliquot 3	99,86
LV20AB4066-5 - Aliquot 4	99,81
LV20AB4066-5 - Aliquot 5	99,76

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Reviewed and electronically signed for Technical Supervisor Approval by
Martina Casini, Employee
for Eurofins Biolab Srl, on 16-Sep-2020 18:04:17 UTC+02:00

CrefoCertSTABLE

UAB Creditreform Lietuva
certifies, that

UAB „Techdentika“
Company code: 302803890

have received
assessment of stable company

Company verification showed that the structure of its solvency is good and more than **five** years fulfills the requirements of CrefoCert STABLE

- CR risk class: 1-4
- Other significant threats for solvency were not detected

Certificate issued: 19.05.2020
Complete information about company http://www.CR.lt

UAB Creditreform Lietuva

Saulius Žilinskas
Director

Jūratė Vaitkienė
Head of Information department

Creditreform

SERTIKA

CERTIFICATE

Certificate registration No. 20K.1687 31 July 2020

This is to certify that the quality management management system designed, implemented, and maintained by

UAB TECHDENTIKA

S. Moniuskos str. 4-5, LT-08122 Vilnius, LITHUANIA

Has been assessed and found to meet the requirements of the standard
ISO 9001:2015
(LST EN ISO 9001:2015)

This certificate is valid for the following scope of operations:

Manufacture of personal protective equipment.

This certificate is valid until 30 July 2023.

Director Ingrida Kusiene

LIETUVOS RESPUBLIKA UAB SERTIKA REPUBLIC OF LITHUANIA

"Sertika" Ltd.
Savanoriu av. 271-255,
LT-50131 Kaunas, Lithuania

sertika@sertika.lt
www.sertika.lt

STATE ENTERPRISE CENTER OF REGISTERS
Lvovo st. 25-101, 09320 Vilnius, Lithuania, ph. +370 5 2688 262, e-mail. info@registrucentras.lt
Data is collected and stored in the Register of Legal Entities, code 124110246

EXTRACT OF BASIC DATA FROM THE REGISTER OF LEGAL ENTITIES OF THE REPUBLIC OF LITHUANIA

2020-05-20 14:13:29

Name:	**Techdentika, UAB**
Code:	302803890
Legal form:	**Private Limited Liability Company**
Legal status:	**No legal proceedings**
Address:	**Vilnius, Moniuskos 4-5**
Registration date:	**2012-06-19**
The rule according to which persons act on behalf of the legal entity:	**Sole representation** **Description (no translation provided):** **Juridinio asmens vardu veikia vadovas**
Manager:	**VYTAUTAS ADOMAITIS, Director**
Contact details:	
MobilePhone No:	**+370 620 20000**
E-mail Address:	**info@techdentika.lt**
Web Site Address:	**www.techdentika.lt**
Version:	**12 (2019-05-31)**
Data status:	**Fully ordered data**

The extract is true and has prima facie authority

Document printed by *Loreta Motiejuniene*

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