



PRODUCT CATALOGUE



Available in packs of various quantities: 5, 10, 50 pcs/pack.



SPECIFICATION:
Product name: Top Safe Disposable Medical Face Mask
Model: DM-101
Type: IIR
Standard: EN14683:2019+AC2019
Appointment: For Professional use



Available in packs of various quantities and various colors: 5, 50 pcs/pack.



SPECIFICATION:

Product name: Protective Face Mask
 Model: DM-100
 Category: PPE Category I
 Standard: EN149:2001+A2009
 Appointment: For Everyday Use
 Color: Light Blue, Pink, Black



EXCLUSIVE EDITION Disposable Black color Face masks.
Available in 25 pcs/pack With Exclusive DMC MASK Design box.



SPECIFICATION:

Product name: Protective Face Mask
Model: DM-100
Category: PPE Category I
Standard: EN149:2001+A2009
Appointment: For Everyday Use
Color: Black



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



Protective Respirators with 4 layer filtration system.
 DM-002 (without air valve), DM-002V (with air valve).
 Available in 2 or 10 pcs/pack.



SPECIFICATION:

Standard: CE 0161, EN 149:2001+A1:2009, COVID-19 PPE-R/02.075-V2

Style: Strap behind ears / Behind the wearer's head* (includes Head Strip Holder)

Filtration efficiency: Above 95% (Equivalent to US N95 and EU FFP2 standard)

Marking: PPE marking, FFP2NR, CE 0161, EN 149:2001+A1:2009, COVID-19 PPE-R/02.075-V2

Designation: NR – Non reusable (single shift use only)

CERTIFICATES



EU type certificate

aitex

CERTIFICATE No. 213782/000161
PPE TYPE: FILTERING HALF MASK FOR COVID-19 PROTECTION ONLY
REF: DM-002

ATEX, notified body No. 0161 for the application of Regulation (EU) 2016/425 of the European Parliament and of the Council of 14 March 2016, in which the essential health and safety requirements that Personal Protective Equipment (PPE) must comply with.

CERTIFIES The Company:
UAB TECHDENTIKA
VITRALGALIS 1B
LT-03228 VILNIUS
 As a manufacturer

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CERTIFICATE No. 213782/000161

Has obtained EU TYPE EXAMINATION in accordance with what is set out in Annex I in Regulation (EU) 2016/425 and in agreement with the applicable test procedures and technical specifications for respiratory protection against COVID-19 only, according to the following standards:

- EN 149:2001+A1:2009

Notifies ATEX notified body No. 0161 for the application of Regulation (EU) 2016/425 and the PPE's Technical Documentation.

Decision on the PPE:
 Filtering half mask without exhalation valve covering nose, mouth and chin, white colour.
 The product has not been tested for EN 149:2001+A1:2009.
 The material that forms the PPE are described in the conformity assessment report #2021ECC005-LIE.

It shall be the manufacturer's responsibility to provide specific information of this certificate and the latest version of protection.

The CE mark on PPE shall only be used in conjunction with one of the conformity assessment procedures according to module C2 or module D described in Article 19(4) of the Regulation (EU) 2016/425.

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EU Declaration of Conformity

REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 14 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC

This is hereby declared that following designated product complies with the essential health and safety requirements of above Council Directive (2) as the approximation of the laws of the Member States relating to it.

MANUFACTURER: TECHDENTIKA, Vilnius, Lithuania
PRODUCT: FILTERING MASK
PRODUCT NAME: DM-002
CLASSIFICATION: CLASS 2
MODEL: DM-002 (Not for reuse)
CERTIFICATE: 2021ECC005-LIE

CONFORMITY ASSESSMENT PROCEDURE: A01 (EN 149:2001+A1:2009)
ASSESSMENT BODY: ATEX 0161 (AITEX)
NOTIFIED BODY INFORMATION: INVESTIGACIJA DE LA INDUSTRIA TEXTIL ATEL, Vilnius, Lithuania
EVALUATION OF THE CONFORMITY: 2021ECC005-LIE

DM-002 is in conformity with the provisions of Regulation (EU) 2016/425, including fulfilment of the applicable requirements and safety requirements set out in Annex I, and with the National Standard Implementing the European Standard EN 149:2001+A1:2009. DM-002 is subject to the conformity assessment procedure Module C2 under conditions of the manufacturer's responsibility.

Signed on behalf of **TECHDENTIKA**
 VILNIUS, LITHUANIA
 Date: 2021.01.27
 General manager VITALIUS ADOMAITIS

This declaration is the responsibility of the Manufacturer
 Document valid until 2021.05.27.

EU Declaration of Conformity

REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 14 MARCH 2016 ON PERSONAL PROTECTIVE EQUIPMENT AND REPEALING COUNCIL DIRECTIVE 89/686/EEC

This is hereby declared that following designated product complies with the essential health and safety requirements of above Council Directive (2) as the approximation of the laws of the Member States relating to it.

Product Name: **DMC MASK**
 Model: **DM-000**

EN149:2001+A1:2009

CE

Category I
 (according REGULATION (EU) 2016/425)

This declaration is the responsibility of the Manufacturer: **Techdentika**
 Address: **Savanoriai ave. 17B, Vilnius, Lithuania**

This declaration applies to all equipment manufactured from a date the model number is indicated. Assessment of conformity of the product with the requirements relating to safety standards and good requirements based above has been performed by manufacturer. Other relevant requirements for product and manufacturing have to be observed.

Signed on behalf of **TECHDENTIKA**
 M. NIUS, LITHUANIA
 Date: 2020.06.30
 General manager VITALIUS ADOMAITIS

Any based Declaration on these products before 2020.10.06 are cancelled.
 Document valid until 2021.05.27.

EU Declaration of Conformity

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

MANUFACTURER: TECHDENTIKA, UAB
MEDICAL DEVICE BRAND NAME: DMC MASK
MODEL: DM-000
CLASSIFICATION: CLASS 2
PRODUCT DESCRIPTION: Medical device covering the mouth and nose providing a barrier to prevent the direct transmission of infectious agents between patient and patient. This medical device is intended for the transmission of infectious agents from staff to patient during the clinical procedure and other medical staff work with similar requirements. A medical face mask with an appropriate mechanical barrier should also be effective in reducing the emission of infectious 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**
 Approval: **CE 0488:2020/AC/2009**
 Type: **IB**
 Test reports: **AR-20-16-0002-01, EUROFINS**
AR-20-16-0002-02, EUROFINS

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

Signed on behalf of **TECHDENTIKA**
 VILNIUS, LITHUANIA
 Date: 2020.10.10
 General manager VITALIUS ADOMAITIS

Any based Declaration on these products before 2020.10.06 are cancelled.
 Document valid until 2021.05.27.

SERTIKA

CERTIFICATE
 Certificate registration No. 20K-1887
 31 July 2020

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

UAB TECHDENTIKA
 S. Monkoskus str. 4-6, 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 Kuteriene**

Number: 140
 Certificate No: 271-208
 LT-09011 Kaunas, Lithuania

eurofins

Method for Determination of Breathability (Differential Pressure)

Test Method EN 14883:2019+AC:2019 Annex C

Number of test specimens: 5
 Number of test per specimen: 5
 Sample area under test: diameter 2.0 cm
 Test area of the test sample: 4.0 cm²
 Flow rate during testing: 60±3 L/min
 General location of measurement areas: Representative of the overall surface

Specimen	Area (cm ²)					Mean value	s.d.
	1	2	3	4	5		
1	275	270	272	269	266	270	20.0
2	278	272	268	269	265	271	16.0
3	286	286	288	285	277	283	15.0
4	278	289	276	280	277	280	13.0
5	267	277	278	280	282	277	14.0
						Mean	
						Standard deviation	13.8

Observation:
 For mask and gill masks the test method may not be suitable as a proper seal cannot be maintained in the sample holder.

ANNEX 1

Figure 1. Disposable mask

ANNEX 2

Fig. 2. Penetration of filter material (F) vs. aerosol particles generated from 2.0% NaCl solution. Overall mask filtration efficiency in terms of particle concentration of particles.

CredCert STABLE

UAB Techdentika
 Vilnius, Lithuania

UAB „Techdentika“
 Korpusas Laisvės 104-105
 LT-08122 Vilnius, Lithuania

ISO 9001:2015
 Certificate No. 271-208
 LT-09011 Kaunas, Lithuania

Valid until 30 July 2023

Director: **Ingrida Kuteriene**

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

