TECHNICAL DATASHEET

MEDICAL DISPOSABLE FACE MASK

3-Folds | 3-Layers | with Elastic Ear-loops

GENERAL INFORMATION

MANUFACTURER

Name: **NEOMATRIX SRL**

Address: #121, 31 August 1989 Street,
MD-2012 Chisinau, Republic of MOLDOVA

Authorized Representative in Moldova:
NEOMATRIX SRL

Authorized Representative
in Romania & European Union:

MATRIX IT SOLUTIONS SRL
str.Bucuresti Nr.230, Biroul Nr.1,
ors. MAGURELE, jud. ILFOV, ROMANIA
VAT-No.: RO30208314
Tel.: / Fax: 021 667 07 11/021 667 07 22
E-mail: info@itmatrix.ro

CONFORMITY ASSESSMENT PROCEDURE

According to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

NOTIFIED BODY

No involvement of a Notified Body is needed for this **Non-Sterile class I device**.

PRODUCT INFORMATION

INTENDED USE

The purpose of this Medical Face Mask is to reduce the risk of infection transfer especially from the person wearing the mask to their surroundings.The product should cover the mouth and nose for providing a barrier to minimize direct transmission of infectious germs between staff and patients.

DESCRIPTION

Rectangular face masks with a shapeable nose piece and two ear-loops on each side to hold mask in place.

Trade Mark: MATRIX

Model: **50-set-masca-faciala-meltblown**
Part Number: **90041**

This product is ***Type IIR mask*** according to European Standard: **EN 14683:2019 + AC:2019**
\+ **ISO 10993 Biocompatibility**, *in vitro cytotoxicity*, *Test method ISO 10993-5-2009*

MATERIAL

Outside Layer: **Spunbonded** Non-woven Polypropylene - (Blue)
Middle Layer: **BFE99 Meltblown** Non-woven Polypropylene - (White)
Inner Layer: **Spunbond** Non-woven Polypropylene - (White)
Nose piece: Plastic covered iron
Elastic Band: Polyester
Latex Free & Fiber-glass Free

DIMENSIONS

Length: 175mm Width 97mm
Length of ear loop: 180mm each
Length of nose piece: 100mm

MANUFACTURING COUNTRY
MADE IN MOLDOVA

REGISTERED IN THE STATE REGISTER OF MEDICAL EQUIPMENT BY THE MEDICINES AND MEDICAL DEVICES AGENCY [AMDM] OF THE REPUBLIC OF MOLDOVA
No.: DM000274414 | Name: "MASCA MEDICALA" [MEDICAL MASK] | Model: "3 STRATURI,NETESUT" | Country: Moldova | Manufacturer: NEOMATRIX SRL | Order No.: Rg04-000218 | Date: 03-Sep-2020

REGULATION & TESTING INFORMATION

REGULATORY INFORMATION

Product CE marked as per 93/42/EEC Directive on Medical Devices & EU Regulation 2017/745.

Class 1 Medical Device - Non-Sterile
Type IIR - Non-Sterile

TEST METHODS

Bacterial Filtration Efficiency (BFE)

When tested in accordance with Annex B of EN 14683, the BFE of the medical face mask shall conform to the minimum value given for the relevant type in Table 1 of EN 14683.

Breathability

When tested in accordance with Annex C of EN 14683, the differential pressure of the medical face mask shall conform to the value given in relevant type in Table 1 of EN 14683.

Microbial cleanliness (Bioburden)

The bioburden of the medical face mask shall be ≤ 30 cfu/g tested. The number of masks that shall be tested is minimum 5 of the same batch/lot.

Differential Pressure

The differential pressure of the medical face mask shall be ≤ 40 cfu/g tested. The number of masks that shall be tested is minimum 5 of the same batch/lot.

TABLE
Performance Requirements for Medical Face Masks

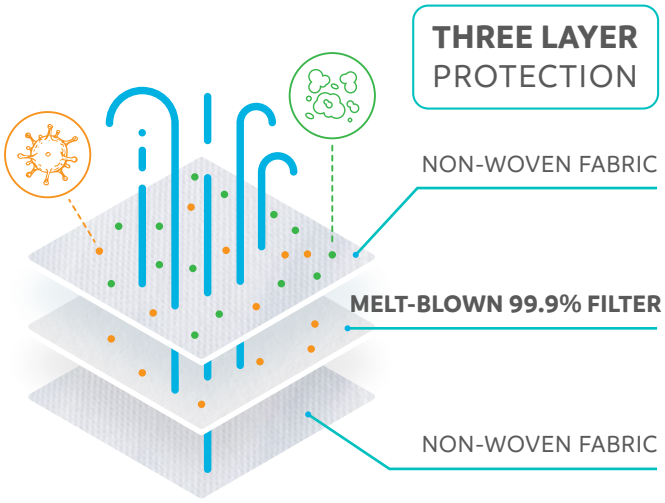
TEST	TYPE I	TYPE II	TYPE IIR	MATRIX MASKS TESTS RESULTS average values
Bacterial Filtration Efficiency [BFE],%	≥95	≥98	**≥98**	**99.9 PASS**
Differential Pressure (Pa/cm2)	<40	<40	**<60**	**31.68 PASS**
Splash Resistance Pressure (kPa)	not required	not required	**≥16,0**	**PASS**
Microbial Cleanliness (cfu/g) [Bioburden]	≤30	≤30	**≤30**	**17.83 PASS**

ADDITIONAL TEST PERFORMED FOR MATRIX MASKS

In Vitro Cytotoxicity Test [MTT Method] according to ISO 10993-5:2009 to test the potential cytotoxicity of the test article	**test article has no potential toxicity to L-929 cells in the MTT Method**

STERILIZATION

This mask is non-sterile



STORAGE

Store in a dry and cool place, away from intense sources of heat. Keep the masks as much as practicably possible in their dispenser box. Keep dispenser boxes as much as practicably possible in their shipper box.

PACKING

Shipping case of 2500 units
50 Units are placed within 1 box and 50 boxes are placed within 1 shipping case

Box dimension:190x100x87mm
Box weight: 170gr
Box matarial: 225gr-paper

Shipping case dimension: 510x390x435mm
Shipping case material: Carton
Shipping case weight: 9kg

SHELF LIFE

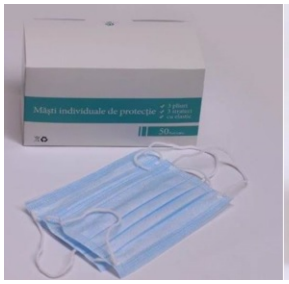
shelf-life is 2 years from production, if stored properly.

The uninterrupted use duration of the device is usually less than 2 hours.

BARCODE

4 840782 288991

VISUALS



REGISTERED IN THE STATE REGISTER OF MEDICAL EQUIPMENT BY THE MEDICINES AND MEDICAL DEVICES AGENCY [AMDM] OF THE REPUBLIC OF MOLDOVA
No.: DM000274414 | Name: "MASCA MEDICALA" [MEDICAL MASK] | Model: "3 STRATURI,NETESUT" | Country: Moldova | Manufacturer: NEOMATRIX SRL | Order No.: Rg04-000218 | Date: 03-Sep-2020

EU DECLERATION OF CONFORMITY

Matrix Medical Disposable Face Mask

Name and address of manufacturer	:	NEOMATRIX SRL #121, 31 August 1989 Street, MD-2012 Chisinau, Republic of Moldova
Product Model	:	50-set-masca-faciala-meltblown
Part Number	:	90041
Brand Name [trade mark]	:	MATRIX
Product Types	:	**Type IIR mask, Medical Device Class I: Non-Sterile, Non-Measuring**
Authorized Representative	:	NEOMATRIX SRL - in the Republic of Moldova
	:	MATRIX IT SOLUTIONS SRL - in Romania & European Union str.Bucuresti Nr.230, Biroul Nr.1, ors. MAGURELE, jud. ILFOV, ROMANIA VAT-No.: RO30208314 | Tel.: / Fax: 021 667 07 11/021 667 07 22 E-mail: info@itmatrix.ro
Intended Use	:	The purpose of this Medical Face Mask is to reduce the risk of infection transfer especially from the person wearing the mask to their surroundings. The product should cover the mouth and nose for providing a barrier to minimize direct transmission of infectious germs between staff and patients.

This declaration confirms that the product meets the essential requirements of following directive(s) and standart(s). The conformity was based on:

Applied Directive(s)	:	Medical Devices Directive 93/42/EEC & EU Regulation 2017/745
Applied Standard(s)	:	**EN 14683:2019 + AC:2019 Medical Face Masks - Requirements and test methods** (including: ISO 22609:2004 | ISO 11737-1:2018 | ISO 10993-5:2009)
International Standards	:	**ISO 9001:2015 (QMS)** *Quality Management System*

The declaration has been carried out in accordance with individual rules and conditions.

Evaluation has been carried out in accordance with:

Test Report(s) No	:	GZHT02395469-S1
Test conducted by	:	Intertek Testing Services Shenzhen Ltd. Guangzhou Branch on behalf of Intertek Deutschland GmbH
Test Lab address	:	3/F., Hengyun Building, 235 Kafa Ave., Guangzhou Economic & Technological Development District, Guangzhou, P.R.C. (510730)
Issue Date	:	18-Mar-2021
Revision Date/No	:	-
Validity Date	:	18-May-2024

* The undersigned herewith declarer that the above-mentioned product(s) meet the provisions of the following EC Council Directives and harmonized standards. All supporting documentation are retained under the premises of the manufacturer.

Chisinau, Republic of Moldova

18-Mar-2021

General Manager,
CIOBANU MIRCEA

Digitally signed by Ciobanu Mircea
Date: 2021.04.06 09:46:55 EEST
Reason: MoldSign Signature
Location: Moldova