EU DECLARATION OF CONFORMITY

V2.0/91186 from **15.04.2021**

Matrix Medical Disposable Face Mask

We, as manufacturer,

Name and address of manufacturer	NEOMATRIX SRL #121, 31 August 1989 Street, MD-2012 Chisinau, Republic of Moldova
with Authorized Representative	MATRIX IT SOLUTIONS SRL - in Romania & European Union str.Bucuresti Nr.230, Biroul Nr.1, 077125 ors. MAGURELE, jud. ILFOV, ROMANIA VAT-No.: RO30208314, Tel/Fax: 0216670711/0216670722, E-mail: info@itmatrix.ro

declare under our sole responsibility, that the following product:

Product Model	**Medical-Mask-TYPE II R_N50**
Part Number	**91186**
Brand Name [trade mark]	**MATRIX**
Product Type classification according to harmonised European Standard EN 14683:2019+AC:2019	**Type II R Medical Face Mask**
Product Type classification according to Medical Devices Directive 93/42/EEC and Regulation (EU) 2017/745	**Class I: non-sterile, non-measuring**
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.

meets all essential technical requirements and is in conformity with the relevant applicable EU legislation

Applied Directive(s)	Council Directive 93/42/EEC concerning medical devices; 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
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**)
Manufacturer's Quality Standard(s)	**ISO 9001:2015 (QMS)** *Quality Management System*

The declaration has been carried out in accordance with conformity assessment procedures for protective equipment.

Assessment has been carried out in accordance with the evaluation of:

Test Report(s) No	GZHT02407734-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	15-Apr-2021
Revision Date/No	-

* The undersigned herewith declares, that the above-mentioned product(s) meet the provisions of the relevant EC Council Directives, Regulations and harmonized standards. All supporting documentation is retained under the premises of the manufacturer.

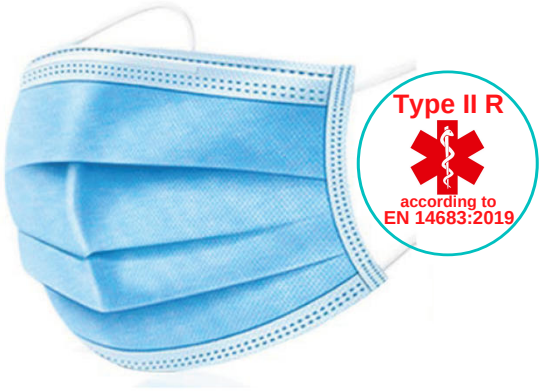
Chisinau, Republic of Moldova
15-Apr-2021

General Manager,
CIOBANU MIRCEA

Digitally signed by Ciobanu Mircea
Date: 2021.04.29 09:32:13 EEST
Reason: MoldSign Signature
Location: Moldova

Digitally signed by Dicusar Vladimir
Date: 2023.09.17 13:02:59 EEST
Reason: MoldSign Signature
Location: Moldova

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
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077125 ors. MAGURELE, jud. ILFOV, ROMANIA
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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 medical face masks with a shapeable nose piece and two ear-loops on each side to hold mask in place.

Trade Mark: **MATRIX**

Model: **Medical-Mask-TYPE II R_N50**
Part Number: **91186**

This product is ***Type IIR Medical Face 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: **Spunbond** 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 & Non-Measurable
Type IIR Medical Face Mask- Non-Sterile

TEST METHODS

Bacterial Filtration Efficiency (BFE)

The ability of the face mask to filter our bacteria so that they are not released into the user's surroundings (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 14683:2019 + AC:2019.

Differential Pressure (Breathability)

The lower this value, the easier it is for the user to breath normally (Pa/cm^2)

The differential pressure for the medical face mask shall be <40 Pa/cm^2 for Type I / Type II masks and <60 Pa/cm^2 for medical face masks Type II R in accordance with Annex C of EN 14683:2019 + AC:2019.

Splash Resistance Pressure

Splash resistance pressure: The ability of the face mask to withstand the penetration of liquid splashes (kPa) [protection from droplets]. No penetration at 16.0 kPa should be attested in accordance to EN 14683:2019 + AC:2019 using ISO 22609:2004 Test method - for resistance against penetration by synthetic blood.

Microbial cleanliness (Bioburden)

The bioburden (microbial cleanliness) of the medical face masks shall be ≤ 30 cfu/g when tested in accordance to Annex D of EN 14683:2019 + AC:2019 and namely 5 test specimens selected randomly from top, bottom and center of the same box/batch/lot.

TABLE
Performance Requirements for Medical Face Masks according to EN 14683:2019+AC:2019

TEST	TYPE I	TYPE II	TYPE II R	MATRIX Medical Mask TESTS RESULTS
Bacterial Filtration Efficiency [BFE],%	≥95	≥98	**≥98**	**99.9 PASS**
Differential Pressure (Pa/cm^2)	<40	<40	**<60**	**47.84 PASS**
Splash Resistance Pressure (kPa)	not required	not required	**≥16,0**	**PASS**
Microbial Cleanliness (cfu/g) [Bioburden]	≤30	≤30	**≤30**	**7.63 PASS**

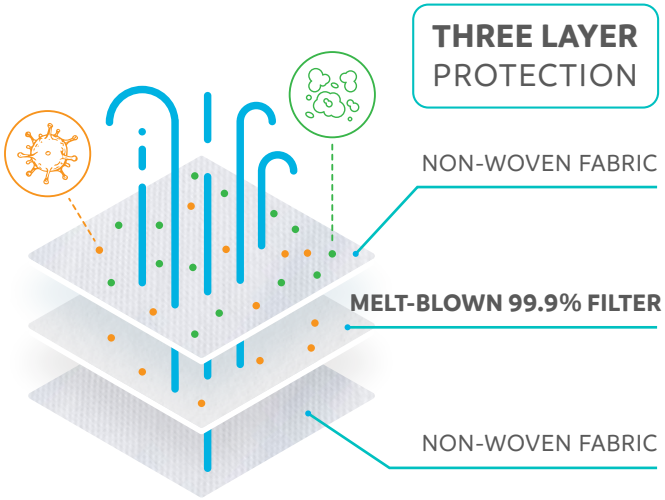
ADDITIONAL TEST PERFORMED FOR MATRIX MASKS

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**

TESTED BY: intertek Total Quality. Assured.

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 shipping case.

PACKING

Shipping case of 2500 Units (masks)
50 Units are placed in 1 [one] box and 50 boxes are placed in 1 [one] Shipping Case

Box dimension:190x100x87mm
Box weight: 170gr
Box material: 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

Type II R
according to EN 14683:2019

VISUALS

REGISTERED IN THE STATE REGISTER OF MEDICAL EQUIPMENT BY THE MEDICINES AND MEDICAL DEVICES AGENCY [AMDM] OF THE REPUBLIC OF MOLDOVA
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