EU DECLARATION OF CONFORMITY

V2.2/91/168-206-218-186 from 29.04.2021

Matrix Medical Disposable Face Mask Type II R

We, as Authorized Representative	**MATRIX IT SOLUTIONS SRL** 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
of the manufacturer *name and address of manufacturer*	**NEOMATRIX SRL** #121, 31 August 1989 Street, MD-2012 Chisinau, Republic of Moldova
declare under our sole responsibility, that the following product:	***MASCĂ FACIALĂ DE UZ MEDICAL TYPE II R DE UNICĂ FOLOSINȚĂ***
Product Model[s]	**Medical-Mask-TYPE II R_N1; Medical-Mask-TYPE II R_N5; Medical-Mask-TYPE II R_N10; Medical-Mask-TYPE II R_N50.**
Part Number[s]	**91168; 91206; 91218; 91186.**
Brand Name [trade mark & logo]	**MATRIX** MATRIX 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 medical device: non-sterile, non-measuring**
Intended Use	The purpose of this Type II R 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* **[Manufacturing of the surgical masks]**

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.

ors. MAGURELE, jud. ILFOV, ROMANIA
29-Apr-2021

General Manager,
MIRCEA CIOBANU

SOCIETATEA COMERCIALA MATRIX IT SOLUTIONS S.R.L. BUCUREȘTI - ROMANIA

Digitally signed by Ciobanu Mircea
Date: 2021.07.01 10:23:39 EEST
Reason: MoldSign Signature
Location: Moldova

BUREAU VERITAS
Certification

NeoMATRIX SRL

#7/1 Nikolai Zelinski Str., MD-2015 Chisinau, Republic of Moldova
Legal address: #121, 31 August 1989 Str., MD-2012 Chisinau, Republic of Moldova

Bureau Veritas Certification Holding SAS – UK Branch certifies that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below

ISO 9001:2015

Scope of certification

Manufacturing of the surgical masks.

Original cycle start date: **29 April 2021**

Certification / Recertification Audit date: **24 February 2021**

Certification / Recertification cycle start date: **29 April 2021**

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **28 April 2024**

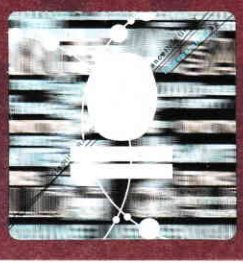
Certificate No. **UA230071** Version: **0** Revision date: **29 April 2021**

Anatoliy Zvon
Signed on behalf of BVCH SAS UK Branch

UKAS MANAGEMENT SYSTEMS
0008

Certification body address: ***5th Floor, 66 Prescot Street, London E1 8HG, United Kingdom***
Local office: ***5th floor, 28, Simon Petlyura St., Kyiv, 01032, UKRAINE***

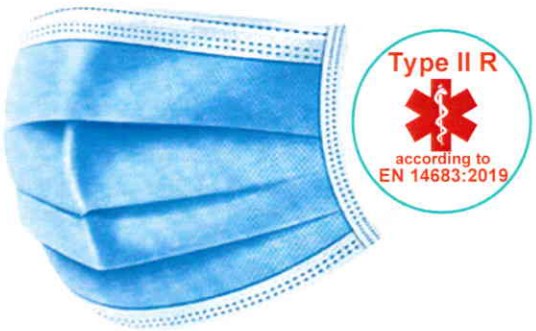
Further clarifications regarding the scope and validity of this certificate, and the applicability of the management system requirements, please call: **+380 44 354 16 00**



TECHNICAL DATASHEET

MATRIX

MEDICAL DISPOSABLE FACE MASK TYPE IIR



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
ISO 9001:2015 Bureau Veritas Certified Company
Quality Management System:
Manufacturing of the surgical masks

Authorized Representative in Moldova:
NEOMATRIX SRL

Authorized Representative
in Romania & European Union:
MATRIX IT SOLUTIONS SRL
str.Bucuresti Nr.230, Biroul Nr.1,
077125 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**.

NON STERILE

MD

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 & logo: **MATRIX** MATRIX MATRIX

Model[s]:**Medical-Mask-TYPE II R_N50|Medical-Mask-TYPE II R_N1**
Medical-Mask-TYPE II R_N10|Medical-Mask-TYPE II R_N5

Romanian: **Masca faciala de uz medical TYPE II R de unica folosinta**

Part Number[s]: **91168; 91206; 91218; 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 100% pure Polypropylene - [blue] 23g/m²
Middle Layer: **BFE99 Meltblown** non-woven Polypropylene - [white] 25g/m²
Inner Layer: **Spunbond** non-woven 100% pure Polypropylene - [white] 23g/m²
Nose piece: Plastic covered iron
Elastic Band: Polyester
Total mask density: 71g/m²
Latex Free & Fiber-glass Free

DIMENSIONS

Length: 175mm Width 97mm [+/- ~3%]
Length of ear loop: 180mm each
Length of nose piece: 100mm

BUREAU VERITAS
ISO 9001:2015
Quality Management System

MANUFACTURING COUNTRY
MADE IN MOLDOVA

NeoMATRIX SRL
str. 31 August 1989, 121
MD-2012, Chişinău,
Republica Moldova

REGULATION & TESTING INFORMATION

REGULATORY INFORMATION

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

Class I Medical Device - Non-Sterile & Non-Measurable Type II R 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/cm²)

The differential pressure for the medical face mask shall be <40 Pa/cm² for Type I / Type II masks and <60 Pa/cm² 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 (ISO 11737-1:2018).

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/cm²)	<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

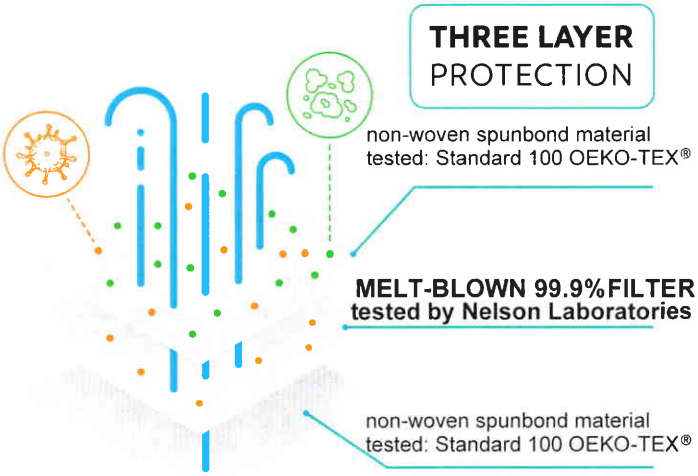
Cytotoxicity In Vitro Cytotoxicity Test [MTT Method] **according to ISO 10993-5:2009 to test the potential cytotoxicity of the test article**	test article has no potential toxicity to L-929 cells in the MTT Method

TESTED BY: intertek Total Quality. Assured.

STERILIZATION

This mask is non-sterile

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

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

SHELF LIFE

shelf-life is 2 years from production, if stored properly.
marked on package:

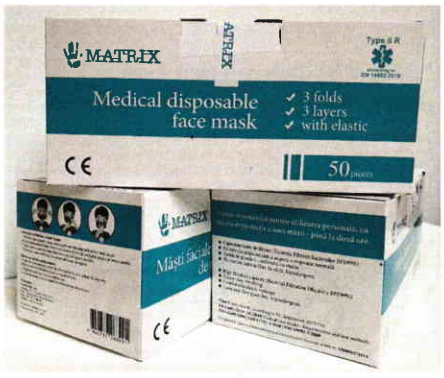
__.202_ month year __.202_ month year

BARCODE

4 840782 288991

Type II R according to EN 14683:2019

VISUALS



INREGISTRAT IN REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE LA AGENTIA MEDICAMENTULUI SI DISPOZITIVELOR MEDICALE (AMDM) DIN REPUBLICA 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