

**EU DECLARATION OF CONFORMITY**

Manufacturer: **MERCATOR MEDICAL S.A.**  
UL. H.MODRZEJEWSKIEJ 30  
31-327 KRAKÓW, POLAND

SRN: PL-MF-000018942

Declares under its sole responsibility that non-sterile examination and protective gloves:

Brand	Type	Sizes	Reference Numbers
<b>nitrylex® beFree long</b>	nitrile, powder free, blue, for single use	XS (5-6) - XL (9-10)	a'100: RD30229001-05
	nitrile, powder free, white, for single use	XS (5-6) - XL (9-10)	a'100: RD30254001-05(0002)
<b>Basic UDI-DI: 5906615 RD NS N PF 9C</b>			
<b>Intended use:</b> gloves intended for use in the medical field to protect patient and user from cross-contamination, intended to be used on one individual during a single procedure.			

meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices, are classified as medical device class I, rule 5, according to Annex VIII of the Regulation (EU) 2017/745 and comply with European standards: EN 455-1:2020+A1:2022, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 15223-1:2021, EN 1041:2008+A1:2013.

The products described above are also Personal Protective Equipment Category III and comply with Regulation (EU) 2016/425 of the European Parliament and the Council of 9 March 2016 on Personal Protective Equipment and resolution of the Council Directive 89/686/EEC and European standards: EN ISO 21420:2020 / EN 420:2003+A1:2009, EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019 / EN 374-4:2013, EN ISO 374-5:2016.

The products described above are subject to the EU Type Examination (Module B) under certificate No. 2777/10013-05/E13-01 issued by notified body:

**SATRA Technology Europe Ltd (2777)**

Bracetown Business Park, Clonee, Dublin 15, Ireland

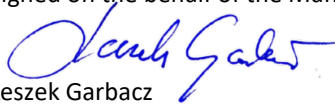
and are subject to the conformity assessment procedure based on quality assurance of the production process (Module D) under surveillance of the notified body:

**BSI Group The Netherlands B.V. (2797)**

Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands

Date and place of issue:  
26.04.2023, Kraków

Signed on the behalf of the Manufacturer:

  
Leszek Garbacz  
Manager Regulacji i Dokumentacji

## INSTRUCTION FOR USE OF PERSONAL PROTECTIVE EQUIPMENT

nitrylex® beFree long

RD30229001-05

The instruction below should be used in conjunction with detailed information on the packaging.

### Short description of the product

Examination and protective gloves, nitrile, powder-free, for single use, non-sterile

### Full description of the product


Reference number : RD30229001-05  
Raw material : nitrile  
Cuff : beaded  
Colour : blue  
Shape : ambidextrous, fitting to the right and left hand  
Size range : XS (5-6), S (6-7), M (7-8), L (8-9), XL (9-10)  
AQL : 1.0  
Quantity in packaging : 100 pcs. by weight  
Shelf life : 3 years (from the date of manufacturing)

### Storage instructions

It is recommended to store the gloves in dry place, in the temperature of 5-35°C and to protect them against direct sunlight.

Keep the gloves in a distance of not less than 1m from heating devices, sources of fire and ozone. Do not keep in direct vicinity of solvents, oils, fuels and lubricants.

### Food contact

Gloves are marked with food contact symbol  and comply with the requirements of Regulation (EU) No 10/2011, European Regulation (EC) No 1935/2004 and with Regulation (EC) No 2023/2006 on Good Manufacturing Practice. Gloves are suitable for handling any type of food and have been tested for Overall Migration Test acc. EN 1186:

Extraction conditions (tested for 1 h in 40°C)	Analysis results [mg/dm <sup>2</sup> ]	Test Result (limit < 10 mg/dm <sup>2</sup> )
50% ethanol	4.6	Pass
3% acetic acid	7.6	Pass
Vegetable oil	<2.0	Pass
Tenax	<2.0	Pass

### MD classification & compliance

Gloves are classified as class I according to Annex VIII of the Regulation (EU) 2017/745 and comply to standards:

EN 455-1:2020+A1:2022, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 15223-1:2021, EN 1041:2008+A1:2013.

### PPE classification & compliance

Gloves are category III Personal Protective Equipment as per Annex I of the Regulation 2016/425 and comply to standards:

EN ISO 21420:2020 / EN 420:2003+A1:2009, EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019 / EN 374-4:2013, EN ISO 374-5:2016.

Notified Body responsible for EU Type Examination (Module B):

Notified Body responsible for on-going conformity (Module D):

**Satra Technology Europe Ltd**  
Bracetown Business Park,  
Clonee, Dublin 15,  
Dublin, Ireland

**CE 2797**

**BSI Group The Netherlands B.V.**  
Say Building, John M. Keynesplein 9,  
1066 EP  
Amsterdam, the Netherlands

Declaration of Conformity and this instruction for use can be found under below web address:

<https://mercatormedical.eu>

### Intended use

These are non-sterile examination and protective gloves for single use, intended for use in medical field to: protect patient and user from cross- contamination, conducting medical examinations, diagnostic and therapeutic procedures and for handling medical contaminated material. Gloves are classified as Medical Devices Class I and as a Personal Protective Equipment Category III. Gloves designed to protect against following risks, among others: substances and mixtures which are hazardous to health and harmful biological agents. Gloves designed to protect against to chemical risk according with EN ISO 374-1:2016+A1:2018 and microorganism (viruses, bacteria and fungi) risks according with EN ISO 374-5:2016. Their design and labelling corresponds to the requirements of the European Regulation 2017/745 on Medical Device and the European Regulation 2016/425 on Personal Protective Equipment. Gloves should be used solely according to their intended application.

### Precautions and indications for use

Dry hands before taking the gloves out from the packaging. Before usage, inspect the gloves for any defect or imperfections. Use at least 1 pair of gloves for one patient and one procedure, these are disposable gloves. Do not let chemical substances get under the gloves through the cuff. If a chemical substance reaches the skin, wash it away immediately with plenty of water. If the gloves get punctured, torn or broken during their use, take them off and put on the new ones. Avoid using gloves dirty in the inside as they may cause irritation leading to skin inflammation or more serious damages.

It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on the temperature, abrasion and degradation. The gloves should not be used in contact with open fire and to protect against any sharp tools. The gloves are not intended for welding, electric shock protection, ionizing radiation or from the effect of hot or cold objects.

The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except in case where glove is equal to or over 400 mm – where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemical is used in a mixture. This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.

When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves.

### Components / hazardous components

Components used in making gloves may cause allergic reactions in some people. Some gloves may contain components known to be a possible cause of allergy for person allergic to them, who may develop contact irritation and/or allergic reaction. In case of an allergic reaction consult a doctor.

### Disposal

The product must be disposed of in accordance with local regulations.

### Manufacturer

MERCATOR MEDICAL S.A.  
ul. H. Modrzejewskiej 30  
31-327 Cracow, Poland  
[www.mercatormedical.eu](http://www.mercatormedical.eu)

## Permeation performance levels as per EN ISO 374-1:2016+A1:2018








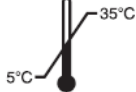















• Level 1 > 10 min • Level 2 > 30 min • Level 3 > 60 min • Level 4 > 120 min • Level 5 > 240 min • Level 6 > 480 min

Test results acc. to EN 16523-1:2015+A1:2018		EN ISO 374-4:2019	Test results acc. to EN 16523-1:2015+A1:2018		EN ISO 374-4:2019
Chemical	Level	Degradation [%]	Chemical	Level	Degradation [%]
40% Sodium Hydroxide (K)	6	2.8	0.1% Phenol	6	9.4
30% Hydrogen Peroxide (P)	4	32.1	n-Heptane (J)	0	45.7
37% Formaldehyde (T)	3	24.5	1.5% Methanol in water	6	-12.3
10-13% Sodium Hypochlorite	6	23.9	70% Isopropanol	0	30.6
50% Sulphuric Acid	6	-50.8	65% Nitric Acid (M)	0	98.4
5% Ethidium Bromide	6	-12.0	99% Acetic Acid (N)	0	97.9
50% Glutaraldehyde	6	4.5	25% Ammonium Hydroxide (O)	0	-8.0

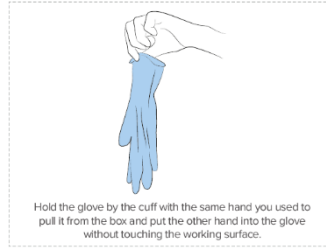
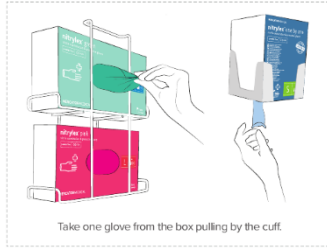
EN ISO 374-4: 2019 Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.

Test acc. To EN ISO 374-2:2019 – Level 2 (ISO 2859)		Test acc. To EN ISO 374-5:2016	
Performance level	AQL	Protection against bacteria & fungi	Pass
Level 3	< 0.65	Protection against viruses	Pass
Level 2	<1.5	EN ISO 374-5:2016 The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.	
Level 1	< 4.0		

## Symbols used on the packaging

	Medical device		Keep dry		Nitrile gloves
	Personal Protective Equipment		Keep away from sunlight		Powder-free gloves
	Manufacturer		Temperature limitation 5-35°C		For single use only
	Lot / batch number		Keep away from ozone		Non-sterile
	Catalogue number		Product quality is not ensured if the package is damaged		Designed to protect against to chemical risks acc. with EN ISO 374-1
	Expiry date		Recyclable packaging		Designed to protect against microorganisms risks acc. with EN ISO 374-5
	Date of manufacture		Package can be treated as municipal waste		Consult instructions for use
	Indicates compliance with the requirements of Ukrainian market		Suitable for food contact (for details check the instruction for use)		

## ■ HOW TO PUT THE GLOVES ON?



## ■ HOW TO TAKE THE GLOVES OFF?

