

## INSTRUCTION FOR USE OF MEDICAL DEVICE AND PERSONAL PROTECTIVE EQUIPMENT

### nitrylex basic

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

<p><b>Description of the product</b></p> <p>Examination and protective gloves, nitrile, powder-free, for single use, non-sterile</p> <p>Sizes : XS, S, M, L, XL, XXL</p> <p>Quantity in packaging : 100 pcs. by weight</p>	<p><b>Precautions and indications for use</b></p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>Gloves are suitable for special purposes as they are examination gloves where risk of wrist injury caused by chemicals is considered to be minimal. Length suitable for tasks that require hand protection. Glove minimum length in accordance to EN 455-2 standard.</p>
<p><b>Storage instructions</b></p> <p>Do not expose to direct sunlight, ozone sources or sources of fire. Store in a dry and cool place, at a temperature of 5-40°C. Do not keep in direct vicinity of solvents, oils, fuels and lubricants.</p>	<p><b>Contraindications</b></p> <p>This product has no known contraindications.</p>
<p><b>Food contact</b></p> <p>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 the food and have been tested for Overall Migration Test acc. EN 1186.</p>	
<p><b>Intended use</b></p> <p>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, preventing perioperative infections during medical procedures (e.g. intravenous, intramuscular, intraarterial injections, dressing changes, wound revision, removal of surgical sutures), conducting medical examinations and medical treatment procedures, conducting diagnostic and therapeutic procedures, for handling medical contaminated material, intended to be used on one individual during a single procedure. Gloves are classified as Medical Devices Class I and as a Personal Protective Equipment Category III. Gloves designed to protect against substances and mixtures which are hazardous to health and against harmful biological agents. Gloves designed to protect against to chemical risk according with EN ISO 374-1 and microorganism (viruses, bacteria and fungi) risks according with EN ISO 374-5. 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.</p> <p>Gloves should be used solely according to their intended use.</p>	
<p><b>Manufacturer</b></p> <p>MERCATOR MEDICAL S.A. ul. H. Modrzewskiej 30 31-327 Kraków, Poland</p> <p>Declaration of Conformity and this instruction for use available under below web address: <a href="https://mercatormedical.eu">https://mercatormedical.eu</a></p>	

Symbols used on the packaging							
	Medical Device		Expiry date		Product quality is not ensured if the package is damaged		For single use only
	Personal Protective Equipment		Date of manufacture		Recyclable packaging		Non-sterile
	Manufacturer		Model number		Package can be treated as municipal waste		Designed to protect against to chemical risks acc. with EN ISO 374-1 [type B]
	Lot / batch number		Keep dry		Suitable for food contact		Designed to protect against microorganisms risks acc. with EN ISO 374-5
	Catalogue number		Keep away from sunlight		Nitrile gloves		Consult instructions for use
	Unique device identifier (UDI code)		Temperature limitation		Powder-free gloves		UA mark

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REF NO: RD302920 01-06

# 3000

### MD classification & compliance

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

EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN ISO 15223-1:2021, EN ISO 20417:2021.

This product is also classified as class I medical device in accordance with Regulation (EU) 2017/745 (Annex VIII), which is confirmed in the EU Declaration of Conformity issued for the product.

### 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 ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016

ISO 374-1/Type B



XVZ

Designed to protect against to chemical risks acc. with EN ISO 374-1 - Type B

Notified Body responsible for EU Type Examination (Module B) and on-going conformity (Module D):

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



### Warning for product users

This product is intended for single use. Do not reuse. Re-use may damage the structure of the product and/or cause it to malfunction, which may result in damage to health. Reuse also poses a risk of product contamination and infection, including the transmission of infectious diseases, which may lead to health damage. Do not use if the packaging has been opened or damaged. Do not use after the expiry date stated on the package label. Do not use if labeling is incomplete or illegible.

### Important information for product user

Any event in the form of a **Product Defect** (i.e. irregularity in the identity, quality, durability, reliability, safety or operation of the product, including malfunctions, operational errors or incorrect information provided by the manufacturer); and/or **Incident** (i.e. means any malfunction or deterioration of properties or performance, including an error in use resulting from the ergonomic features of the device made available on the market, as well as any irregularities in the information provided by the manufacturer and any adverse effects) should be reported to the manufacturer of the device at [regulatory@pl.mercatormedical.eu](mailto:regulatory@pl.mercatormedical.eu) Any **serious incident, serious adverse event or serious risk to public health** that occurs in connection with the device must be reported to the manufacturer and to the competent authority of the Member State of establishment of the user and/or patient.

### Shelf life of product

5 years from manufacturing date

### Long-term storage instructions

It is recommended to store product in dry place, in temperature of 5-40°C and to protect them against direct sunlight. Keep product 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.

### Transport instructions

Transport in conditions ensuring an appropriate hygienic standard, protecting product against dirt. The product is not thermolabile - changing conditions regarding temperature or humidity in the short-term transport period do not affect the usability of the product or its properties or safety of use in any way. The product does not require transport in controlled conditions in terms of temperature and humidity (confirmed on the basis of accelerated aging tests and risk analysis).

### Product disposal

If product has been used and has come into contact with body fluids or infectious substances, product should be disposed of as a contaminated product.

Otherwise, the product should be disposed of as mixed waste.



Dispose of in the black container

### Packaging disposal

Carton packaging made of homogeneous material, does not contain different types of materials, does not require separation into fractions. The packaging is 100% recyclable.

### Transport carton disposal

Carton packaging made of homogeneous material, does not contain different types of materials, does not require separation into fractions. The packaging is 100% recyclable.



Packaging for disposal - dispose of in the blue container



Packaging for disposal - dispose of in the blue container

### Warnings about potential allergic reactions

Components used in gloves production process 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. During the production process, the following chemical accelerators and antioxidants may be used, which may cause potential allergic reactions type IV:

- I. Zinc dibutyldithiocarbamate (ZDBC)
- II. Zinc diethyldithiocarbamate (ZDEC)
- III. Poly(dicyclopentadiene-co-p-cresol)

This information is included in this manual based on requirements of EN 455-3:2023 standard - Disposable medical gloves - Requirements and tests in biological evaluation. The product has been tested in accordance with EN ISO 10993-5,10, and has not shown any cytotoxic, irritating or skin sensitizing effects.

### REACH information

The products covered by this instruction do not contain substances listed in the latest version of the candidate list according to Regulation (EC) 1907/2006; These products also do not contain substances with carcinogenic, mutagenic or reproductive toxic effects (substances defined in Regulation (EU) 2017/745, Annex 1, Section 10.4.1) They do not contain polycyclic aromatic hydrocarbons (PAH) (substances defined in EN ISO 21420, p. 4.2. f); and phthalates, plasticizers containing phthalates, thiurams. The products do not contain natural rubber latex.

**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	-68.1	37% Formaldehyde (T)	5	9.5
30% Hydrogen Peroxide (P)	2	30.5			

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)**

Performance level	Level 3	Level 2	Level 1
AQL	< 0.65	< 1.5	< 4.0

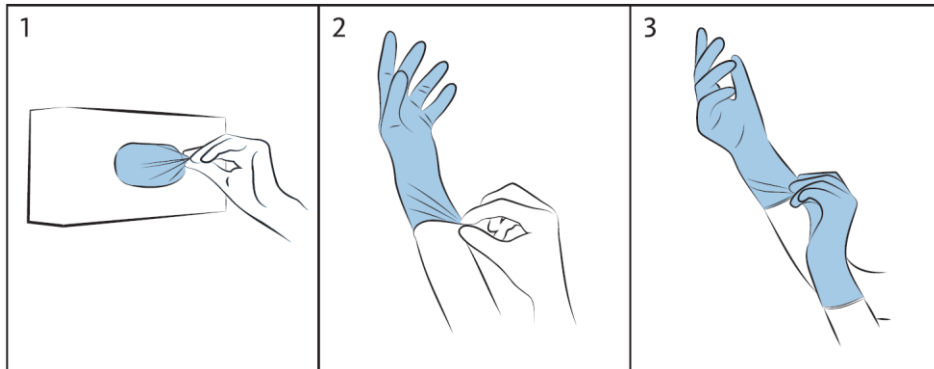
**Test acc. to EN ISO 374-5:2016**

Protection against bacteria & fungi	Pass
Protection against viruses	Pass

EN ISO 374-5:2016 The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.

Testing in accordance with ISO 16604:2004 procedure B.

**How to put the gloves on?**



**How to take the gloves off?**

