

























INSTRUCTION FOR USE OF PERSONAL PROTECTIVE EQUIPMENT

nitrylex basic

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

Description of the product	Precautions and indications for use
<p>Examination and protective gloves, nitrile, powder-free, for single use, non-sterile</p> <p>Sizes : XS, S, M, L, XL</p> <p>Quantity in packaging : 100/200 pcs. by weight</p> <p>Shelf life : 3 or 5 years from manufacturing date depends on LOT number (see the packaging)</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>
Storage instructions	
Do not expose to direct sunlight, ozone sources or sources of fire. Store in a dry and cool place, at a temperature of 5-35°C. 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 the food and have been tested for Overall Migration Test acc. EN 1186.	
Intended use	
<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, 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 substances and mixtures which are hazardous to health and against harmful biological agents. Gloves designed to protect against 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>	
Manufacturer	
<p>MERCATOR MEDICAL S.A. ul. H. Modrzejewskiej 30 31-327 Kraków, Poland</p>	<p>Declaration of Conformity and this instruction for use available under below web address: https://mercatormedical.eu</p>
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.	

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

nitrylex basic

REF NO: RD301050 01-06; RD300840 01-06; RD301060 01-06; RD300980 01-06

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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+A1:2022, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 15223-1:2021, EN ISO 20417:2021.

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



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

XYZ

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

CE 2777

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)

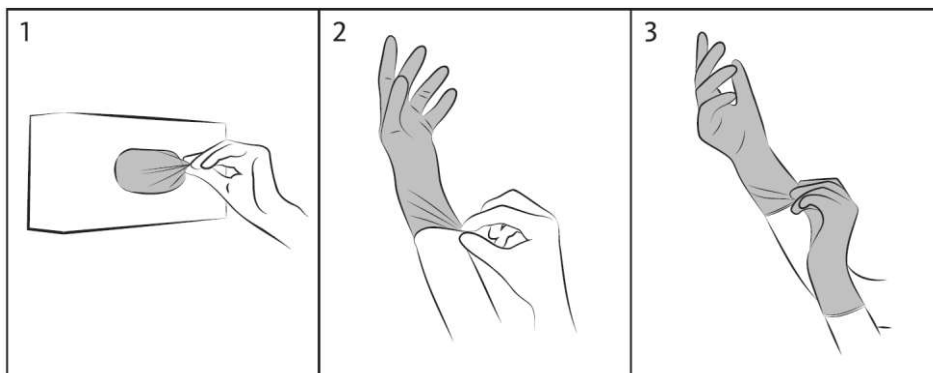
Performance level	Level 3	Level 2	Level 1
AQL	< 0.65	<1.5	< 4.0

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.

How to put the gloves on?



How to take the gloves off?

