### **MERCATOR** MEDICAL



# nitrylex<sup>®</sup> black

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

Intended use

#### Short description of the product

Nitrile examination and protective gloves, powder-free, non-sterile for

disposable use	
Full description of the produ	ct
Raw material	: nitrile
External surface	: fingertip textured, polymerized
Internal surface	: polymerized, chlorinated
Cuff	: beaded
Colour	: black
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 and fluorescent light. Recommended relative humidity in the room where the gloves are stored is  $60 \pm 20\%$ .

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  $\times$  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/dm²]	Test Result (limit < 10 mg/dm²)
3% acetic acid	3.1	Pass
10% ethanol	4.7	Pass
Olive oil	5.1	Pass

MDD classification & compliance

Gloves are classified as class I Medical Device as per Annex IX of the Council Directive 93/42/EEC and comply to standards:

EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 15223-1:2016, 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 420:2003+A1:2009, EN ISO 374-1:2016 (Type B), EN 374-2:2014, EN 16523-1:2015, EN 374-4:2013, EN ISO 374-5:2016.

Declaration of Conformity can be found under below web address: https://mercatormedical.eu/produkty/rekawice/diagnostyczne/nitrylex-black

Notified Body 2777 responsible for EU Type Examination (Module B) and Module C2 On-going Conformity: Satra Technology Europe Ltd Bracetown Business Park, Clonee Dublin 15, Dublin, Ireland These are non-sterile examination and protective gloves for single use, intended for use in medical field to: protect patient and user from crosscontamination, 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. Their design and labelling corresponds to the requirements of the European Medical Device Directive 93/42/EEC 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 putting the gloves on. 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 with soap. 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. 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.

This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals. Degradation results indicate the change in puncture resistance of the gloves after exposure to challenge chemical. 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 and to the tested specimen. It can be different if the chemical is used in a mixture. The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.

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.

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.

Gloves are suitable for special purposes as they are examination gloves where risk of injury to the wrist is considered to be minimal, gloves are shorter than EN 420 min. length requirement.

#### Components / hazardous components

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, seek medical assistance immediately.

#### Disposal

Used gloves can be contaminated with contagious or other hazardous substances. They should be disposed of in accordance with local regulation. Gloves should be buried or burned under controlled conditions.

#### Manufacturer

MERCATOR MEDICAL S.A. ul. H. Modrzejewskiej 30 31-327 Cracow, Poland www.mercatormedical.eu

CE2777



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				levels as per EN ISO 374-1:2016		. 400	
<b>T</b> h.		> 30 min		• Level 4 > 120 min • Level 5 > 2		> 480 min	EN 274 4 2042
	acc. to EN 16523-1:2015		EN 374-4:2013	Test results acc. to E	N 16523-1:2015		EN 374-4:2013
	emical	Level	Degradation [%]			Level	Degradation [%]
35% Ethanol		6	55.0	50% Sulphuric Acid		6	21.1
40% Isopropanol		6	68.7	5% Ethidium Bromide		6	32.9
10% Acetic Acid		4	53.5	3% Hydrogen Peroxide		6	44.0
50% Benzalkonium Chlo	ride*	6	29.5	30% Hydrogen Peroxide (P)		2	52.8
4% Chlorhexidine Diglue	conate**	6	32.9	37% Formaldehyde (T)		5	20.0
10% Phosphoric Acid		6	14.0	50% Glutaraldehyde		6	22.9
40% Sodium Hydroxide	(К)	6	2.6	0.1% Phenol		6 24.7	
12% Sodium Hypochlorite 6		22.7			· · · ·		
*minimum detectable permeati	on rate: 5 μg/cm²/min			**minimum detectable permeation rat	te: 7 μg/cm²/min		
Test ac	c. To EN 374-2:2014 – Level 2	(ISO 285	9)	Tes	t acc. To EN ISO 3	74-5:2016	
	ormance level AQL	<u></u>	- ,	Protection against		Pass	
	Level 3 < 0.65			Protection against bacteria & rungi Protection against viruses		Pass	
	Level 2 <1.5			Totection	n against virases	r ass	
				-			
	Level 1 < 4.0						
			Symbols used	d on the packaging			
(2)	Do not re-use / gloves are intended for single use		NON STERILE	Non-sterile gloves		Powdered gloves	
	Do not use, if package is damaged		713	Keep away from solar and fluorescent light		Powder free gloves	
$\sim$					<b>X</b>		
	Keep away from moisture,		-35°C	Temperature limitation /	POLYMER COATED	Presence	e of polymer coating on
	store in a dry place		5°C	gloves store in temperature 5-		the inne	r surface of the glove
LATEX Raw material – natural rubb		ber	Ŏ,	35°C Keep away from ozone	COSMETIC COATING	Presence of cosmetic coating on the inner surface of glove	
<b>REF</b> Catalogue number			LOT	Lot / batch number	SILK	Presence of silk coating on the inner surface of glove	
EC REP	EU Authorised Representative symbol should be accompanie by name and address of Authorised Representative			Expiry date	TEXTURED	Presence of external texture on the glove	
ISO 374-5:2016	Marking of gloves protecting against bacteria and fungi.			Gloves protecting against chemical dangers with digit literal odes	NITRYL	Gloves made from nitrile	
	Marking of gloves protectir against viruses, bacteria an fungi.		Ľ,	Antistatic gloves	VINYL	Gloves n	nade from vinyl
ISO 374-1/Type A	Marking o type A chemical resis gloves. Six tested chemicals sha identified by their code letter u pictogram.	all be		Date of manufacture	NEOPREN	Gloves n	nade from neoprene
ISO 374-1/Type B	Marking o type B chemical resis gloves. Three tested chemicals be identified by their code lette under pictogram.	shall	***	Manufacturer, symbol should be accompanied by name and address of Manufacturer	POLIIZOPREN	Gloves n	nade from polyisoprene
ISO 374-1/Type C	Marking o type C chemical resis gloves.	stant		Consult instructions for use	by weight	50 glove	s by weight
	Protective glove against mecha risk (if applicable accompanied digit code of relevant performa levels)	by 4	1 4 I N	Package made from paper, qualify for recycling	M 100 by weight	100 glov	es by weight
ΓÏ,	Food contact symbol (article is suitable for food contact, for de check the instruction for use)	etails	Ì	Package is treated as municipal waste	by weight	200 glov	es by weight
PG	Indicates compliance with t requirements of Russian market	he		Indicates compliance with the requirements of Ukrainian market	A D	Additona side of p	al information on inner ackage

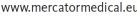
User instructions Rev. 1.3, August 2019

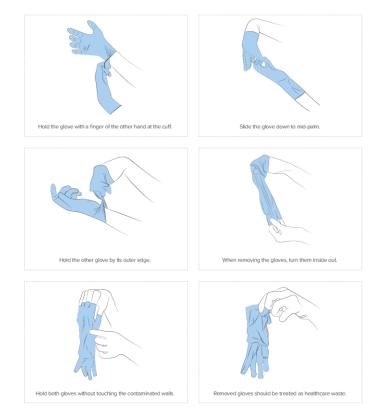


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### ■ HOW TO TAKE THE GLOVES OFF?



Hold the glove by the cuff with the same hand you used to pull it from the box and put the other hand into the glove without touching the working surface.

### ■ HOW TO PUT THE GLOVES ON?

ke one glove from the box pulling by the cuff.



