



nitrylex® sterile

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

Short description of the product

Nitrile examination and protective gloves, powder-free, sterile, for single use.

MDD classification & compliance.

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

EN 455-1:2000, EN 455-2:2009+A2:2013, EN 455-3:2006, EN 455-4:2009, EN ISO 15223-1:2016, EN 1041:2008, EN 556-1:2001, EN ISO 11135:2007.

MDD 93/42/EEC
DNV GL Presafe AS
Notified Body No.: 2460
Veritasveien 3
N-1363 Høvik, Norway



PPER classification & compliance

Gloves are category I Personal Protective Equipment as per Annex I of the Regulation 2016/425 and comply to standard EN 420:2003+A1:2009.

Contraindication for use of the gloves

- (a) Do not use package is damaged or wet.
- (b) Risk of reuse: Do not reuse, reuse can cause cross infection and compromise safety.
- (c) Possibility of usage of non sterile gloves.
- (d) "Gloves shall not be worn where there is a risk of entanglement by moving parts of machines" is needed.
- (e) The results do not reflect the actual duration of protection in the workplace due to other factors influencing the performance, such as temperature, abrasion, degradation etc.

Warnings

- (a) Storage information : Keep away from sunlight. Store in cool dry place, away from direct light & ozone.
- (b) Device disposal should be done as per local regulatory norms.
- (c) Do not re-sterilize.

Intended use

This disposable medical device is made up of synthetic rubber latex which is ambidextrous, intended to be used for conducting medical examination, diagnostic and therapeutic procedures, provides barrier against potentially infectious fluids and other contaminants.

Indication for use of the gloves

1) Dry hands thoroughly before donning.

2) Glove Opening and Donning Procedure:

(a) Remove the walled gloves (inner wrapper) from the Pouch (outer wrapper) either by:

- Tear down along the 'V' cut for plastic pouch (tear down to open pouch), or;
- Peel open from the corner for paper pouch (peel down to open pouch).

(b) Open the walled glove to see „left” and „right” compartment.

(c) Pinch back upper and lower flaps of the inner wrapper.

(d) Using the middle flaps, open the wrapper touching only 1 inch margin for safety.

(e) Be sure wrapper does not close over gloves after opening to avoid contamination.

(f) Using the thumb and the first two fingers of the non-dominant hand, pinch the cuff of the folded edge of the glove cuff for the dominant hand, touching only the inside surface of the glove.

(g) Slide dominant hand in to the gloves keeping hand point downwards and pull up to wrist.

(h) Using the glove hand insert the 4 fingers under the cuff of the other glove and pull the glove up to the arm.

(i) Adjust the gloves as necessary.

3) Glove Removal Procedure:

(a) Take hold of the first glove at the wrist.

(b) Fold it over and peel it back, turning it inside out as it goes. Once the glove is off, hold it with your gloved hand.

(c) To remove the other glove, place your bare fingers inside the cuff without touching the glove exterior. Peel the glove off from the inside, turning it inside out as it goes. Use it to envelope the other glove.

Manufacturer, EC REP & Importer

Manufacturer: KANAM Latex Industries Pvt. Ltd.

12-67C, Ananthanadarkudy

Asaripallam P.O., Nagercoil 629 201

Kanyakumari District, Tamil Nadu, India

3/13F, West Peruvilai road,

Pallavilai, Nagercoil 629 003

Tamil Nadu, India

EC REP: EMERGO EUROPE

Prinsessegracht 20

2514 AP The Hague

The Netherlands

Importer: MERCATOR MEDICAL S.A.







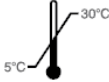















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Symbols used on the packaging

	Gloves sterilized by ethylene oxide		Do not re-sterilize		Gloves made from nitrile
	Do not re-use / gloves are intended for single use		Keep away from moisture, store in a dry place		Powder free gloves
	Temperature limitation / gloves store in temperature 5-30°C		Keep away from solar and fluorescent light		Keep away from ozone
	Catalogue number		Lot / batch number		EU Authorised Representative, symbol should be accompanied by name and address of Authorised Representative
	Manufacturer, symbol should be accompanied by name and address of Manufacturer		Date of manufacture		Expiry date
	50 pairs of gloves		Do not use, if package is damaged		Consult instructions for use
	Package made from paper, qualify for recycling		Package is treated as municipal waste		Indicates compliance with the requirements of Ukrainian market
	Indicates compliance with the requirements of Russian market				