



santex[®] powdered

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

Short description of the product

Sterile, natural rubber latex surgical gloves, powdered, for disposable use

Full description of the product

Reference number	: RC11050060-90
Raw material	: natural rubber latex
Donning powder	: modified corn starch (USP)
External surface	: textured
Internal surface	: powdered
Cuff	: beaded
Colour	: light creamy
Shape	: anatomic, hand specific
Size range	: 6.0; 6.5; 7.0; 7.5; 8.0; 8.5; 9.0
AQL	: 1.0
Sterilization	: Ethylene oxide (EO)
Packaging	: 1 pair per pouch, 50 pairs per dispenser, 400 pairs per carton
Shelf life	: 5 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.

It is recommended to protect the gloves against humidity. Keep the gloves in a distance of not less than 1m from heating devices, sources of fire and ozone.

MDD classification & compliance

Gloves classified as medical device – class IIa under Council Directive 93/42/EEC.

Compliance with standards: EN ISO 13485:2016, EN ISO 14791:2012, EN ISO 15223-1:2016, EN 1041:2008, EN 455-1:2000, EN 455-2:2009+A2:2013, EN 455-3:2006, EN 455-4:2009, EN 556-1:2001|AC:2006, EN ISO 11737-1:2006, EN ISO 11737-2:2009, EN ISO 11135-1:2007, EN ISO 11138-2:2009, ISO 10993-1:2009|AC:2010, EN ISO 10993-5:2009, EN ISO 10993-7:2008, EN ISO 10993-10:2010.

DNV GL Presafe AS, Notified Body Number 2460:

CE 2460

Declaration of Conformity can be found under below web address:
<https://en.mercatormedical.eu/>

Intended use

Sterile, surgical gloves, made from natural rubber latex, with thumb positioned towards the palm side of the index finger which reduces the fatigue on the hands, intended to be worn on the hands usually in surgical settings to provide barrier against potentially infectious fluids or other contaminants and to protect the patient by ensuring sterility of the wound environment. These gloves are intended for single use only. Gloves are classified as Medical Devices Class I. Their design and labelling corresponds to the requirements of the European Regulation 2017/745 on Medical Device. Gloves should be used solely according to their intended application.

Precautions and indications for use

Attention should be drawn to the fact that the confirmed protection level does not reflect the real working conditions where other factors may influence the protection level, for example, abrasion, degradation, atmospheric conditions. Users should take care when using the gloves. Using them solely according to their intended application. These are sterile gloves for single use only and are not intended for cleaning or re-sterilization. The protection is limited to the hand only, the results relate to the palm of gloves and there were tested under laboratory condition.

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. Natural rubber latex gloves may cause allergic reactions including anaphylactic reactions. 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

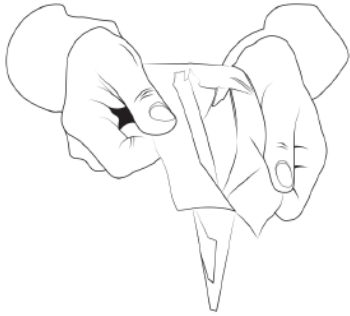


Symbols which can be used on the packagings

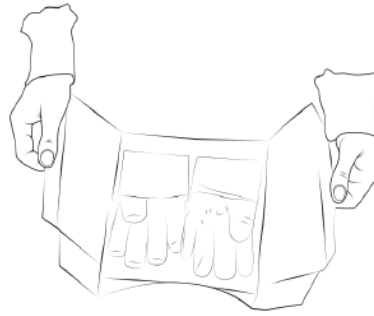
	Do not re-use / gloves are intended for single use		Powdered gloves		Glove is fitting the right hand
	Sterilized with Ethylene oxide		Powder free gloves		Glove is fitting the left hand
	Sterilization with Gamma		Presence of polymer coating on the inner surface of the glove		the number of pairs of gloves in the envelope (1)
	Do not re-sterilize		Marking of gloves protecting against bacteria and fungi		the number of pairs of gloves in the dispenser (25)
	Raw material – natural rubber latex		Marking of gloves protecting against viruses, bacteria and fungi		the number of pairs of gloves in the dispenser (50)
	Raw material – neoprene		Marking of type A chemical resistant gloves. Six tested chemicals shall be identified by their code letter under pictogram		the number of pairs of gloves in the carton (100)
	Raw material – nitrile		Marking of type B chemical resistant gloves. Three tested chemicals shall be identified by their code letter under pictogram		the number of pairs of gloves in the carton (300)
	Lot / batch number		Marking of type C chemical resistant gloves		the number of pairs of gloves in the carton (400)
	Catalogue number		Keep away from moisture, store in a dry place		the number of sets of gloves in the dispenser (25)
	Manufacturer, symbol should be accompanied by name and address of Manufacturer		Keep away from solar and fluorescent light		the number of sets of gloves in the carton (200)
	EU Authorised Representative, symbol should be accompanied by name and address of Authorised Representative		Temperature limitation / gloves store in temperature 5-35°C		Consult instructions for use
	data produkcji		Keep away from ozone		Do not use, if package is damaged
	Expiry date		Package made from paper, qualify for recycling		Package is treated as municipal waste
	Indicates compliance with the requirements of Russian market		Indicates compliance with the requirements of Ukrainian market		



Donning surgical gloves guideline



1) Open the packaging and remove the inner sachet containing the gloves.



2) Holding it by the wings, open the sachet.



3) Holding the exposed inside cuff of the left glove with the right hand, put on the glove.



4) Insert the left, gloved hand into the cuff opening of the right glove.



5) Pull the glove onto the right hand.



6) Pull the gloves up over the cuffs of the gown.