

## Product Descriptions

Raw Material	: Natural Rubber Latex
Size range	: XS , S, M , L ,XL
Design	: Ambidextrous
Cuff	: Beaded
Sterile Status	: Non Sterile
Single Use or Reusable	: Single Use
Shelf Life	: 5 years (from the date of manufacturing)

## Storage instruction

Storage in cool, dry place away from direct sunlight, in the temperature of range 5-30° C

Glove characteristics will not be changed significantly on storage, when it is stored as per recommended storage conditions.

## PPE Regulation 2016/425 classification & compliance

The gloves are category III personal protective equipment as per Annex I of the Regulation 2016/425.

Standards complied:- ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN 16523-1:2015, EN ISO 374-4:2019, EN ISO 374-5:2016. EU Type Examination (Module B) and conformity to type based on quality assurance of the production process (Module D))

Declaration of conformity can be found under below web address:

<https://www.stmarysrubbers.com/>

## Instruction for use

Dry hands before donning. Choose the glove based on your palm width.

For single use only, not intended for cleaning

Risk of reuse: May cause infection, allergic reaction and poor barrier protection.

The protection is limited to the hand only, the results relate to the palm of gloves and there were tested under laboratory condition.

Before usage, inspect the gloves for any defect or imperfections, if there are defects like holes, tear and any colour change, discard the glove presenting such defects. Also during usage if the gloves punctured or broken, discard the glove and use new ones.

This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.

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.

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.

The penetration resistance has been assessed by laboratory conditions and relates only to the tested specimen.

Avoid chemical substances get under the gloves through the cuff. If a chemical substance reaches the skin, wash it away immediately with plenty of water.

## Caution

This product contains natural rubber latex which may cause allergic reactions in some individuals. In case of latex allergy discontinue use and consult a physician.

This glove does not protect the user from mechanical injuries, cold objects, heat or fire. It is also not intended for protection against electric shock, and radiation.

## Warnings

- The performance levels obtained in permeation testing does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals
- The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except in cases where the 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
- 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 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
- Before usage, inspect the gloves for any defect or imperfections
- For single use only

**Permeation level and Degradation as per EN ISO 374-1:2016+A1:2018**

Permeation by liquid chemical test acc. to EN 16523-1:2015		Resistance to degradation as per EN ISO 374-4 :2019
Chemical	Level	
Sodium Hydroxide 40 %	Level 6	3.2
Acetic acid 50 %	-	5.2
Formaldehyde 37%	-	2.8
Other chemicals		
Sulphuric acid 10 %	Level 6	-53.4
Acetic acid	Level 6	-52.3

• 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 acc. EN ISO 374-5:2016**
























Protection against bacteria & fungi	Pass
Protection against viruses	Pass


**Protective gloves against chemicals and micro-organisms: Determination of resistance penetration as per EN ISO 374-2:2019 as sampling plan ISO 2859**

Level: 1

\*Level 3 < 0.65 AQL    \*Level 2 < 1.5 AQL    \*Level 1 < 4.0 AQL

**Descriptions of the labels symbols**

	Do not re-use		Consult Instructions for Use		Importer
	Non –Sterile		Contains or presence of latex rubber		Size
	Expiry Date		CE Mark for Medical Device		Lot/Batch No
	Compliance with the requirements of Ukrainian Market		Authorized representative in The European Community (Emergo Europe)		Manufacturer (St.Marys Rubbers Pvt Ltd)
	Date of Manufacture		Unique Device Identification		REF Number
	Keep away from sun light		Keep Dry		Temperature limit
	Medical Device		Caution		Made in India (3 Letter refer to country code )
 In Compliance With Personal Protective Equipment Reg.(EU) 2016/425 (Category III)		CE Marking for PPE	 ISO 374-5:2016 VIRUS	Protective gloves against dangerous chemicals and micro-organisms	

<p>ISO 374-1/Type C</p> 	<p>Permeability as per 374-1 symbol to be Type C: Protective glove with permeation Performance, Level 2 against one test chemical.</p>
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## Manufacturer

## EC Rep Address

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