

## **Product Descriptions**

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Raw Material	: Natural Rubber Latex
Size range	: 5, 5½, 6, 6½, 7, 7½, 8, 8½, 9 & 9.5
Color	: Primary Gloves-Underglove, Secondary Gloves- Creamy White
Design	: Anatomical, hand specific
Cuff	: Beaded
Sterile Status	: Sterile
Sterilization type	: Ethylene oxide/Gamma radiation (Based on customer requirement)
Single Use or Reusable	: Single Use
Shelf Life	: 3 Years

## **Storage instruction**

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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**

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

Standards complied:- EN ISO 21420:2020+A1:2024, EN ISO 374-1:2016+A1:2018(Type B), EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, 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/>

## **Notified Body details for Module B and Module D certificates**

Notified Body Name : SGS Fimko Ltd  
Address : Takomotie 8, FI-00380 Helsinki, Finland ,t.+358 9 696 361  
Notified Body Number: 0598  
Web address : [www.sgs.fi](http://www.sgs.fi)

## **Instruction for use**

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Dry hands before donning. Choose the glove based on your palm width. Single use on one individual during a single procedure. 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 presentingsuch 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. This product consists of two pairs of gloves: the primary glove and the secondary glove, which are designed to be worn one over the other, providing an additional layer of protection with enhanced durability and safety. The primary and secondary gloves are packaged together in a single pouch, but each glove is wrapped inside its own separate wallet. The primary gloves are sterile latex surgical under glove powder free which is green in color and the secondary glove is sterile latex surgical gloves powder free which is in light brown color. The color differentiation between the gloves makes it easier to detect breaches or perforation in the outer glove, immediately alerting the user. Both Primary gloves and Secondary gloves should be worn and is not intended to be used alone.

## **Caution**

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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.

Sterile until package is opened or damaged.

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.

## **Warning**

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- The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.”
- Single use on one individual during a single procedure

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

Permeation by liquid chemical test acc. to BS EN 16523-1:2015+A1:2018			Resistance to degradation as per EN ISO 374-4 :2019	
Chemical	Level			
	Primary Gloves	Secondary Gloves	Primary Gloves	Secondary Gloves
Sodium hydroxide 40% (CAS No:1310-73-2)	Level 6	Level - 6	-5.9	-22.2
Hydrogen peroxide 30% (CAS No:7722-84-1)	Level 6	Level- 2	4.3	-8.8
Formaldehyde 37% (CAS No:50-00-0)	Level 4	Level- 2	9.0	5.8

• 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**

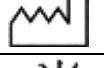
Protection against bacteria & fungi	Pass
Protection against viruses	Pass

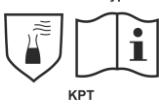
**Protective gloves against chemicals and micro-organisms: Determination of resistance penetration as per EN ISO 374-2:2019 as sampling plan ISO 2859**

Level: 3

\*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		Do not Re-sterilize
	Sterilized by ethylene oxide		Contains or presence of latexrubber		Size
	Expiry Date		CE Marking for Medical devices		Lot/Batch No
	Do not use if package is opened or damaged		Authorized representative in The European Community (Emergo Europe)		Manufacturer (St.Marys Rubbers Pvt Ltd)
	Date of Manufacture		Unique Device Identification		Sterile Barrier System
	Keep away from sun light		Keep Dry		Temperaturelimit
	Medical Device		Caution		Made in India (3 Letter refer to country code )
	Importer		Sterilized using Gamma Irradiation		One pair
	In Compliance With Personal Protective Equipment Reg.(EU) 2016/425 (Category III)	CE Marking for PPE	 ISO 374-5  VIRUS	Protective gloves against dangerous chemicals andmicro-organisms	

 EN ISO 374-1/Type B KPT	Permeability as per 374-1 symbol to be Type B: Protective glove with permeation Performance, Level 2 against minimum three test chemical.	 REF	REF Number
	Compliance with the requirements of Ukrainian Market	 Allergen IV	Allergen- IV symbol

 **Manufacturer**

St.Marys Rubbers Pvt Ltd  
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 Kottayam, Kerala, India - 686518  
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