INSTRUCTION FOR USE
Non Sterile Latex Examination gloves Powdered

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^{o} 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, After donning remove powder by wiping gloves thoroughly with a sterile wet sponge, sterile wet towel or other effective method. 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

Size and measurement of gloves as per ISO 21420:2020

Declared Size	Average hand circumference (mm)	Sizing as per ISO 21420:2020
S	161	6
M	194	7.5
L	211	8
XL	227	8.5

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**	**7.5**
Acetic acid 50 %	**-**	**21.2**
Formaldehyde 37%	**-**	**10.7**
Other chemicals		
Sulphuric acid 10 %	**Level 6**	**8.8**
Acetic acid 10%	**Level 6**	**8.7**

• 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	Non –Sterile	LATEX	Contains or presence of latex rubber		Size
	Expiry Date	CE	CE Mark for Medical Device	LOT	Lot/Batch No
	Compliance with the requirements of Ukrainian Market	EU REP	Authorized representative in The European Community (Emergo Europe)		Manufacturer (St.Marys Rubbers Pvt Ltd)
	Date of Manufacture	UDI	Unique Device Identification	REF	REF Number
	Keep away fromsun light		Keep Dry	30°C 5°C	Temperaturelimit
MD	Medical Device		Caution	IND	Made in India (3 Letter refer to country code)

CE 0598 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 andmicro-organisms
ISO 374-1/Type C	Permeability as per 374-1 symbol to be Type C: Protective glove with permeation Performance, Level 2 against one test chemical.		

Manufacturer

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