1. Product Description

Sterile Latex Examination Gloves powdered are manufactured from natural rubber latex and supplied in Small, Medium & Large sizes. It is Sterilized by Ethylene Oxide. Ambidextrous with straight fingers and beaded cuff. Pre-powdered with absorbable corn starch U.S.P. Manufactured under hygienic condition. Conforms to ASTM D 3578, EN 455 and ISO 11193-1 standards. Products have shelf life of 5 years from the date of manufacturing. Gloves compounded primarily from natural rubber latex (Type-1). Beaded and long cuff gloves. Creamy white in colour. Free from dirt marks, oil stains, embedded foreign particles, coagulum etc. Textured at fingertip area. The cuff shall fit closely without being constructive and it shall not roll back or ruckle while in use. Nontoxic and non-irritant. Single Use Gloves dimensions comply EN 455 /ASTM D 3578 standards.

2. Intended Use

Manufactured from natural rubber latex. Gloves intended for use in the medical field to protect patient and user from cross-contamination, conducting medical examinations, diagnostic and therapeutic procedures and for handling contaminated medical materials. The gloves are designed for transient use and are intended to be used in conjunction with invasive procedures.

3. Medical Device Qualification

Device Type	Non-active Device
Human Usage	To be used alone for human beings, for one or more the specific medical purpose
Medical Purpose	Prevention of disease (A barrier against potentially infectious materials and other contaminants).

4. Medical Device classification demonstration

Parameter	**Definition**
Duration of Use	Transient (<60 Minutes)
Invasiveness	Invasive device
Device Type	Non-active Medical Device
Rule Applicable	05 - All invasive devices with respect to body orifices
Classification	Is

Reference	In accordance with MDCG 2021-24 & Annex VIII of EU Medical Device Regulation 2017/745

5. Personal Protective Equipment Regulation Classification and Compliance

The Sterile Latex Examination Gloves Powdered is classified as PPE under EU Regulation 2016/425, Module B. The Sterile Latex Surgical Gloves Powdered complies the requirements of PPE standards EN ISO 374-2:2019, EN ISO 374-4:2019, EN 16523-1:2015+A1:2018, ISO 21420:2020, ISO 3071:2020, ISO 16604:2004.

6. Material Physical Description

Natural rubber (NR) latex collected from the Hevea trees exists as a colloidal suspension. This sap can be further refined and compounded to render it more readily processed and to optimize physical properties. Products manufactured from natural rubber latex tend to be very pure and have the enhanced physical properties that natural rubber latex are known for –outstanding elongation, tear properties and recovery. The most ideal temperature range when using latex is between -55 degrees Celsius and 82 degrees Celsius. Gloves are made by immersing moulds in an extract of natural rubber latex.

7. Material Chemical Description

Physical State:	Liquid
Specific Gravity:	0.95-0.96
Boiling Point:	100 C
Density (g/ml):	0.92
Odour:	Ammonia Odor
Vapour Pressure:	730 mm Hg
Freezing Point:	0 C
Appearance:	Milky Liquid
pH:	10-11

8. Mechanical and Physiochemical characteristics

Physical Dimensions (ASTM D 3578:2019, EN 455-2:2015)

Size	Length (mm) Min	Palm Width (mm)	Thickness (mm) Min	
			Palm	Finger
Extra Small	240 mm	≤80	0.08	0.08
Small		80 ± 10		
Medium		95 ± 10		
Large		110 ± 10		
Extra Large		≥ 110		

PHYSICAL PROPERTIES

Characteristics	Before Ageing	After Ageing 70 ± 2° C for 168 hrs.
ASTM D 3578:2019		
Tensile Strength (Mpa) min.	18	14
Ultimate Elongation (%) min.	650	500
Stress at 500% Elongation (Mpa) Max.	5.5	NA
EN 455-2:2015		
Minimum force at break (N)	≥ 6	≥ 6
Total protein content	< 200 mg/dm^2, Test method-ASTM D 5712-15(2020)	
Powder content	< 10 mg/ dm^2, Test method-ASTM D 6124-06(2017)	
Bacterial endotoxin	< 20 EU	

9. Device Variant List

#	Variant Name	Variant Description/Details
1.	Sterile Latex Examination Gloves – Powdered	Extra Small (XS), Small (S), Medium (M), Large (L), Extra Large (XL)

10. Guidance regarding choice of right size of gloves

- It's important to find the correct sizing to ensure the optimal levels of comfort and tactility.
- Glove size measures in inches, so a tape measure to find the right size gloves for the hands.
- To find out glove size, wrap a measuring tape around the widest part of hand (excluding thumb)
- Measure from the tip of the middle finger to the base of the hand
- Use the largest of these two measurements for the correct size glove (e.g.: If your hand measures 6.5 - 7 inches, choose size 7.

11. Duration of Use

Duration of Use is Transient Use (<60 minutes). If the device is used continuously for more than 60 minutes, there is chance for infections. User should change the gloves hourly once.

Refer Risk Management Report (SMR/RMF/03).

12. Medical Indication

- Protection of the wearer from contamination with blood, Secretions and excretions and the associated risk of contamination with pathogens capable of reproduction.
- Prevention of pathogen release from the hand into sterile work area during aseptic duties
- Protection from chemicals
- Defined pathogen barrier as protection from biological agents.
- Act as a barrier protection for chemicals as well as microorganisms

13. Contraindication

- Sterile Latex Examination Gloves Powdered contain Powder content, persons who are sensitive to powder may develop allergy towards the powder content
- Latex gloves are made of Natural rubber latex, which may cause allergic reactions including Latex Allergy – Anaphylactic if the user is allergic to latex.
- Gloves contain Natural Latex; persons who are sensitive to Latex should consult a physician before using

14. Intended User

Doctors, nurses, caregivers, dentists and other healthcare Professionals can use the Examination gloves

15. Target Patient Population

It can be used in all patient population except in patients with known allergy to natural latex rubber.

16. Precaution and Warnings

- After donning remove powder by wiping gloves thoroughly with a sterile wet sponge, sterile wet towel or any other effective method
- This product contains natural rubber latex which may cause allergic reaction such as latex allergy, including anaphylactic responses in some individuals
- Store in a cool, dry place and away from direct sunlight
- Do not Re-sterilize – Re-sterilization can cause product damage / Contamination
- Do not Re Use - Reuse can cause infection, allergic reaction and poor barrier protection.
- For transient use only
- Dispose after use as per hospital policies or country's regulatory norms
- Do not use if the pouch is torn or sterility is compromised
- Glove is not used in handling food and cytoxic agents.
- Double gloving is not recommended, double gloving is done for procedures with contact with large amounts of blood or body fluids, for some high-risk orthopaedic procedures.

17. Condition not involving glove usage of direct and indirect patient exposure

Direct Patient Exposure: Taking blood pressure, temperature and pulse; performing Subcutaneous and Intramuscular injections; bathing and dressing the patient; transporting patient; caring for eyes and ears (without secretions); any vascular line manipulation in absence of blood leakage.

Indirect Patient Exposure: Using the telephone; writing in the patient chart; giving oral medications; distributing or collecting patient dietary trays; removing and replacing linen for patient bed; placing non-invasive ventilation equipment and oxygen cannula; moving patient furniture.

Contact Precaution**:** When indicated, use of medical gloves is recommended as part of contact precautions, to reduce the risk of pathogen dissemination to the patient's environment, to other patients and for the protection of healthcare workers.

Reference: glove-use-information-leaflet.pdf (who.int)

18. Direction for Use

- Select the appropriate size Gloves for the hands
- Take out the Wallet from the pouch by peeling it off at the site of direction for open
- Put hand through the glove opening
- Adjust the gloves as needed
- After donning remove powder by wiping gloves with a sterile wet sponge or any other effective methods.
- Must check the date of manufacturing and expiry date before using

19. Side Effects/Adverse Events

Powder allergy, itching, rashes, inflammation, pain, latex allergy, skin redness, ulcerated skin, peeling skin and hypersensitivity type-I reaction.

20. Residual Risks

Latex Allergy (Type-I Allergy, Anaphylaxis), Infections, Inflammation, Respiratory tract & pulmonary diseases, Toxic to environment, Poor product properties, Poor dexterity, Puncture or perforation to the gloves

21. Clinical Benefits

NRL or Natural Rubber Latex Gloves:

- Are competent barrier to protect against infections for both healthcare professionals and the patients.
- Are easy to put on comfortable to wear and provide adequate, durable protection.
- Have less after-use defects.
- Has significant greater satisfaction with regard to factors such as quality, safety and durability.
- Have good barrier integrity.

- Have good fit and comfort
- Have high tear propagation strength
- Have high tensile strength

22. Disposal Instruction

Dispose after use as per hospital policies or country's regulatory norms.

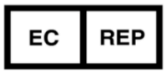
23. How Gloves are Supplied

Gloves are supplied as a pair

24. Storage condition

Storage of gloves should be in between 5°c - 30°c.

25. Symbols used on Label

	Do not re-use		Consult Instructions for Use		Do not Re-sterilize
	Sterilized by ethylene oxide		Contains or presence of latex rubber		Size
	Expiry Date		CE Mark		Lot/Batch No
	Do not use if package is opened or damaged		Authorized representative in the European Community (Emergo Europe B.V, Westervoortsedijk 60, 6827 AT, Arnhem, The Netherlands))		Manufacturer (St. Marys Rubbers Pvt Ltd)
	Date of Manufacture		Unique Device Identification		Sterile Barrier System

	Keep away from sun light		Keep Dry		Temperature limit
MD	Medical Device				

26. Revision History

Revision No	Changes Incorporated	Effective Date
00	Initial Release	07.04.2022
01	1. Added section 3 (Medical Device Qualification) and section 4 (Medical Device Classification) 2. Updated section 11 (Duration of Use) 3. Added section 9 (Device Variant List) 4. Added section 6, 7 and 8 (Physical and chemical Description including length, width specifications; Powder content& specification) 5. Added PPER - personal protective equipment regulation classification & compliance in section 5. 6. Protection against chemical and microorganism is updated in section 12 7. Storage temperature is updated in section 24 8. Guidance regarding choice of right size of gloves is updated in section 10. 9. Details of protein and powder specification is updated in section 8. 10. Use of this gloves in Contact precaution; handling cytotoxic agents, food etc updated in section 16 11. Conditions not involving glove usage of direct and indirect patient exposure is updated in section 17 12. Use when the sterility is	23.06.2023

	compromised or the package is torn is updated in section 16 13. Reference for details/ steps to be taken if the surgical procedures takes more than one hour is provided in section 11 14. Double Glove use addressed in section 16. 15. Contact precaution is updated in section 17. 16. Product description updated as per technical file in section 1	
02	Updated residual risks in section 20	22.09.2023