1. Product Description

The Sterile Latex Surgical Gloves Powdered are manufactured from natural rubber latex and supplied in various sizes 5.5 to 9.0. The Latex surgical gloves- powdered is sterilized by ETO gas or Gamma radiation as per customer requirements. EO Sterilized by validated process cycle as per ISO 11135:2014, amendment 1:2018 and gamma sterilization is validated as per EN ISO 11137-1: 2015+A2:2019. The Gamma sterilized products have a shelf-life of 03 years and ETO sterilized products have a shelf life of 05 years from the date of manufacturing. Anatomically shaped medical gloves with the thumb positioned towards the palmar surface of the index finger rather than lying flat (Hand Specific). Micro-roughened textured finish in inner palm and in inner part of finger area which provides good grip at wrist and in curved fingers. Beaded cuff gloves. Pre-powdered absorbable corn starch for powdered gloves. Single use gloves. Gloves compounded primarily from natural rubber latex (Type-1). Free from dirt marks, oil stains, embedded foreign particles, coagulum etc. The physical properties, dimension and tensile strength of the material are as per EN 455, ISO 10282, ASTM D 3577 and IS 13422. The Sterility Assurance Level (SAL) is 10^{-6}. Biologically compatible as per ISO 10993-Part 5, 7, 10 & 11. Nontoxic and non-irritant. Size of the gloves is embossed on the palm area. Passes Viral Penetration test as per ASTM F 1671.

2. Intended Use

This single use sterile surgical Gloves-Powdered is intended for use in surgical procedures and to be worn once and then discarded. The glove is worn on the hand of surgeon and healthcare personnel to prevent contamination between healthcare personnel and the patient's body, fluids, waste or environment. The gloves are designed for transient use and are intended to be used in conjunction with invasive procedures. The glove is pre powdered with absorbable corn starch for easy donning. Bio-absorbable corn starch is generally accepted as a safe donning agent.

3. Medical Device Qualification

Parameter	Definition	Reference	Justification
Device Type	Non-active Device	EU MDR 2017-745, Article 2 – Point 1	Latex Surgical Gloves are identified as an "Non-active Medical Device" and does not require any external power to complete its defined intended use.
Usage Type	Standalone	EU MDR 2017-745, Article 2 – Point 1	Latex Surgical Glove is used as alone and does not require any other accessory or a medical device support to complete its intended use.
Medical Purpose	Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease.	EU MDR 2017-745, Article 2 – Point 1	The latex surgical gloves are used to protect the user (Surgeon or Medical Professionals or Healthcare Provides) and/or the patient from spread of infection or illness during medical procedures ad examinations.

4. Medical Device classification demonstration

Parameter	Definition
Duration of Use	Transient Normally intended for continuous use for less than 60 minutes.
Continuous Use	The Latex Surgical Gloves are to be replaced immediately with another of the same type gloves during surgical procedures performed more than 60 minutes.
Invasiveness	Surgically invasive device The Latex Surgical Glove is an invasive device which penetrates inside the body through the surface of the body, including through mucous membranes of body orifices with the aid or in the context of a surgical operation; and a device which produces penetration other than through a body orifice.
Device Type	Non-active Medical Device

Parameter	Definition
Rule Applicable	Rule 6 - Surgically invasive intended for transient use
Classification	IIa
Reference	In accordance with MDCG 2021-24 Guidelines & Annex VIII of EU Medical Device Regulation 2017/745

5. Personal Protective Equipment Regulation Classification and Compliance

The Sterile Latex Surgical 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 374-1:2016 + A1:2018, EN ISO 374-5:2016, 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

#	Property	Specification
1.	Appearance	Milky Liquid
2.	Odor	Ammonia odor
3.	Physical state	Liquid
4.	Boiling point	100 °C
5.	Specific Gravity	.95 - 0.96
6.	Vapour Pressure	730 mmHg
7.	Ph	10-11

8. Mechanical and Physiochemical characteristics

PHYSICAL DIMENSION (ASTM D 3577: 2019, EN 455-2:2015, IS: 13422:1992, ISO 10282:2014)

Size	Length (mm)	Palm Width (mm)	Thickness (in mm)					
			Cuff (Min)		Palm (Min)		Finger (Min)	
	Min	Specification	Standard	SMR	Standard	SMR	Standard	SMR
5½	250	70 ± 6	0.10	0.11	0.10	0.14	0.10	0.16
6	275	76 ± 6						
6 ½		83 ± 6						
7	275	89 ± 6						
7 ½		95 ± 6						
8		102 ± 6						
8 ½	280	108 ± 6						
9		114 ± 6						

PHYSICAL PROPERTIES:

Characteristics	Before Ageing	After Ageing 70 ± 2° C for 168 hrs.

ASTM D 3577:2019, IS 13422:1992		
Tensile Strength (Mpa) min.	24	18
Ultimate Elongation (%) min.	750	560
Stress at 500% Elongation (Mpa) Max.	5 .5	NA
EN 455-2:2015		
Minimum force at break	9.0 N	9.0 N
Total protein content	< 200 µg/dm^2 ,Test method-ASTM D 5712-15(2020)	
Powder content	< 15 mg/ dm² , Test method-ASTM D 6124-06(2017)	
Bacterial endotoxin	< 20 EU	

9. Device Variant List

#	Variant Name	Variant Description/Details
1.	Sterile Latex Surgical Gloves – Powdered	5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5 & 9.0

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 mm, 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 size 6.5 - 7, choose size 7 (89 ± 6mm).

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 a high chance for puncture or perforation of the gloves. User should change the gloves hourly once.

Refer Risk Management Report (SMR/RMF/01).

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 the surgical Site during surgery.
- Defined pathogen barrier as protection from biological agents.
- Act as a barrier protection for microorganisms

13. Contraindication

- Sterile Latex Surgical 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

Healthcare Surgeons, Operation Theatre Personnel and Healthcare Professionals for the patients at high risk of infections.

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 wet sterile sponge 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, surgical site infection, latex allergy, skin redness, ulcerated skin, peeling skin, hypersensitivity type-I reaction

20. Residual Risks

1. Latex Allergy (Type-I Allergy, Anaphylaxis)
2. Infections (Blood-Borne Infection, Post-operative wound infection)
3. Inflammation, Allergic reaction
4. Respiratory Diseases (Powder induced granulomas, dyspnea due to powder allergy respiratory diseases)
5. Toxic to environment
6. Poor dexterity, Puncture or perforation to the gloves.

21. Clinical Benefits

NRL or Natural Rubber Latex Gloves:

- NRL gloves are competent barrier to protect against infections for both healthcare professionals and the patients.
- NRL gloves provide lower rates of perforation and lower viral leakage rates.
- NRL gloves are easy to put on comfortable to wear and provide adequate, durable protection.
- NRL gloves have good barrier integrity.
- NRL gloves have less after-use defects.
- NRL Gloves has significant greater satisfaction with regard to factors such as quality, safety and durability.
- NRL gloves have high tear propagation strength
- NRL gloves have low perforation rate
- NRL gloves have high tensile strength
- NRL gloves have good fit and comfort

22. Disposal Instruction

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

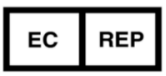
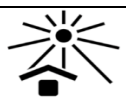
23. How Gloves are Supplied

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 Prinsessegracht 20, 2514 AP The Hague, 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
	Sterilized by Gamma radiation		Medical Device		

26. Revision History

Revision No	Changes Incorporated	Effective Date
00	Initial Release	07.04.2022
01	Updates as per TR comments: 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. Residual risks; Blood borne infection and post-operative wound infection is updated in section 20. 11. Use of this gloves in Contact precaution; handling cytotoxic agents, food etc updated in section 16 12. Conditions not involving glove usage of direct and indirect patient exposure is updated in section 17 13. Use when the sterility is compromised or the package is torn is updated in section 16	23.12.2022
02	1. Reference for details/ steps to be taken if the surgical procedures take more than one hour is provided in section 11. 2. Double Glove use addressed in section 16. 3. Contact precaution is updated in section 17. 4. Product description updated as per technical file in section 1 5. Residual risk updated in section 20.	23.06.2023
03	1. USP is removed from section 1 and 2 2. Inches is changed to mm in section 10 3. Act as a barrier for chemical is removed from section 12	18.12.2023
04	1. Updated residual risk in section 20 and clinical benefits in section 21 as per revised risk management file 2. Updated UDI symbol in section 25	12.02.2024