

 ST. MARYS RUBBERS PVT. LTD.	ST. MARYS RUBBERS PVT.LTD	Doc No: SMR/IFU/SLSGPF
	Instruction For Use- Sterile Latex Surgical Gloves Powder Free	Revision No: 02
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1. Product Description

The Sterile powder free latex surgical gloves (Polymer coated) are manufactured from natural rubber latex and supplied in various sizes from 5.5 to 9.0. The gloves are made powder free by polymer coating process. The Latex surgical gloves- powder free 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. 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

Single use sterile surgical Gloves-Powder Free 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 made powder free by polymer coating method.

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
Rule Applicable	Rule 6 - Surgically invasive intended for transient use
Classification	IIa

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Parameter	Definition
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 Powder free is classified as PPE under EU Regulation 2016/425, Module B. The Sterile Latex Surgical Gloves Powder Free 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 latex – A milky fluid that consists of extremely small particles of rubber obtained from plants, mainly from the rubber tree, dispersed in an aqueous medium. Products are then formed from natural rubber latex by dipping, extruding, or coating via the natural rubber latex (NRL) process.

7. Material Chemical Description

S. No	Properties	Specification
1.	Physical state	Liquid
2.	Odour	Ammonia Odour
3.	Appearance	Milky Liquid
4.	Specific Gravity	0.95-0.96
5.	Vapour pressure	730 mmHg
6.	Boiling point	100 C
7.	Freezing Point	0 C
8.	pH	10-11
9.	Density (g/ml)	0.92
10.	Storage Temperature	5 – 25 C
11.	Storage Humidity	70 – 75%

8. Mechanical and Physiochemical characteristics

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

Size	Min. Length (mm)	Palm Width (mm)	Min. Thickness (mm)					
			Cuff		Palm		Finger	
			Standard	SMR	Standard	SMR	Standard	SMR
5 ½	250	70 ± 6	0.10	0.11	0.10	0.14	0.10	0.16
6	275	76 ± 6	0.10	0.11	0.10	0.14	0.10	0.16
6 ½	275	83 ± 6	0.10	0.11	0.10	0.14	0.10	0.16
7	275	89 ± 6	0.10	0.11	0.10	0.14	0.10	0.16
7 ½	275	95 ± 6	0.10	0.11	0.10	0.14	0.10	0.16
8	275	102 ± 6	0.10	0.11	0.10	0.14	0.10	0.16
8 ½	280	108 ± 6	0.10	0.11	0.10	0.14	0.10	0.16
9	280	114 ± 6	0.10	0.11	0.10	0.14	0.10	0.16

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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)	
Bacterial endotoxin	< 20 EU	

9. Device Variant List

#	Variant Name	Variant Description/Details
1.	Sterile Latex Surgical Gloves – Powder Free (Polymer Coated)	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 6.5 - 7, 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 a high chance for puncture or perforation of the gloves. User should change the gloves hourly once.

Refer Risk Management Report (SMR/RMF/02).

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.
- 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.

13. Contraindication

- 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

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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

- 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 cytotoxic 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 gloves 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

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, cross contamination, Allergic reaction, Inadequate barrier protection
3. Inflammation
4. Toxic to environment
5. Poor dexterity, Puncture or perforation to the gloves

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21. Clinical Benefits

NRL or Natural Rubber Latex Gloves:

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

22. Disposal Instruction

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











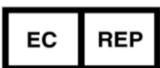









23. How Gloves are Supplied

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	<ol style="list-style-type: none"> 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 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 	23.06.2023
02	<ol style="list-style-type: none"> 1. Inches is changed to mm in section 10 2. Act as a barrier for chemical is removed from section 12 3. Updated UDI Symbol in section 25 4. Updated Residual Risk in section 20 and Clinical Benefits in section 21 	21.02.2024