1. Product Description

The Sterile Latex Surgical Gloves Powder Free are manufactured from natural rubber latex (Type-1) and supplied in various sizes 5.5 to 9.0. It is Sterilized by Ethylene Oxide or Gamma radiation based on the customer requirement. Gloves are coated with unique blend of polymer to provide excellent donning capability. It is anatomically shaped with micro rough surface in palm and finger area. The glove is creamy white to pale yellow in colour (Natural colour). The Ethylene oxide sterilized product is having shelf-life of 5 years and the gamma sterilised product is having shelf life of 3 years from the date of manufacturing. Each glove has non-detectable levels of chemical residue. It is sterilized by validated process cycle and the Sterility Assurance Level (SAL) is 10^{-6}. It passes Viral Penetration test as per ASTM F 1671. Glove is biologically compatible as per ISO 10993-Part 5 ,7,11 & 10 and it is nontoxic, non -pyrogenic and non-irritant.

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. Duration of Use

Duration of Use is Transient Use (<60 minutes)

4. 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

5. 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

6. Intended User

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

7. Target Patient Population

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

8. 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

9. 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
- Must check the date of manufacturing and expiry date before using

10. Side Effects/Adverse Events

Itching, rashes, inflammation, pain, surgical site infection, latex allergy, skin redness, ulcerated skin, peeling skin, hypersensitivity type-I reaction

11. Residual Risks

Latex Allergy (Type-I Allergy, Anaphylaxis), Infections (Blood-Borne Infection, Post-operative wound infection), Inflammation and Toxic to environment

12. 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

13. Disposal Instruction

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

14. How Gloves are Supplied

Gloves are supplied as a pair.

15. Symbols used on Label

	Do not re-use		Consult Instructions for Use		Do not Re-sterilize
STERILE EO	Sterilized by ethylene oxide	LATEX	Contains or presence of latex rubber		Size
	Expiry Date	CE	CE Mark	LOT	Lot/Batch No
	Do not use if package is opened or damaged	EC REP	Authorized representative in the European Community (Emergo Europe)		Manufacturer (St.Marys Rubbers Pvt Ltd)
	Date of Manufacture	Unique Device Identification	Unique Device Identification		Sterile Barrier System
	Keep away from sun light		Keep Dry	30°C 5°C	Temperature limit
STERILE R	Sterilized by Gamma radiation	MD	Medical Device		