

**Latex Examination Gloves-Powdered**

**DEVICE INTENDED USE:**

It is used to protect the patient and users from cross infection during examination, check-up, treatment and handling of contaminated medical materials except for surgery.

**DEVICE NAME, CATALOGUE NO AND BRAND NAME:**

Device Name	Catalogue no.	Brand Name
Latex Examination Gloves	EXMLPE	NULIFE, NUFIT, NUFLOW, MEDI-AID, NURAZ, DEN-V, PREMIERCARE, SANTE, SFM, BB , CARE GLOVES, SUPREME, BENESIT, SAFETEX, STARGLOVE

**DEVICE SIZES:**

Device Name	Sizes
Latex Examination Gloves	Extra-Small, Small, Medium, Large, Extra-Large

**BASIC UDI:**

8905159EXMLPW9Z

**DEVICE DESCRIPTION:**

**Latex Exam Gloves – Powdered.**

A disposable device made of natural latex intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. Non-sterile medical examination gloves, which may or may not be anatomically shaped. These gloves are powdered. Examination gloves are intended for conducting medical examinations, diagnostic and therapeutic procedures and for handling contaminated medical material.

**INTENDED USER:**

Healthcare professionals.

**TARGET PATIENT POPULATION:**

These examination gloves are used for all patient population for examination procedures only.

**DEVICE SHELF LIFE:**

5 years from the date of manufacture printed on the product label

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## **Latex Examination Gloves-Powdered**

### **STORAGE INSTRUCTION:**

It is recommended to store the gloves in cool, dry place, in the temperature range of 10°C to 30°C and to protect them against direct sunlight.

### **INDICATIONS:**

- 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 exam site.
- Defined pathogen barrier as protection from biological agents.

### **WARNINGS AND PRECAUTIONS:**

1. Do not use after the expiry date printed on the label.
2. Do not use if the Package is opened or damaged. Use of product whose package is opened, or damage may cause inflammation.
3. Do not Re Use. The reuse of the gloves may cause severe complications such as cross contamination, dermatitis, loss of physical properties, infection, allergic reaction and poor barrier protection.
4. Latex gloves are made of Natural rubber latex, which may cause allergic reactions including Latex Allergy – Anaphylactic if the user is allergic to latex.
5. Gloves may contain excess powder residues which may cause respiratory tract disease.
6. Single Use mentioned on Sales Packaging Label.
7. Device should not be stored in direct sunlight
8. Device disposable should be done as per local regulatory norms.

### **CONTRA INDICATIONS:**

1. Gloves contain Powder content, persons who are sensitive to powder may develop allergy towards the powder content
2. Latex gloves are made of Natural rubber latex, which may cause allergic reactions including Latex Allergy – Anaphylactic if the user is allergic to latex.

### **DIRECTION FOR USE:**

- Select the appropriate size Gloves for the hand.
- Take out the Gloves from the pouch by peeling it off at the site of direction for open.
- Wear the gloves Left hand & Right Hand.
- Must check the date of manufacturing and expiry date before use.
- Adjust the gloves as needed.

#### **A) How to Don Gloves:**

- Rubbing the hand with alcohol or wash with water

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## **Latex Examination Gloves-Powdered**

- Dry hands before donning the gloves.
- Take out gloves from single unit packaging.
- Gloves need to be donned carefully; do not apply excessive force to pull the gloves when donning.
- Keep the fingernails short and change gloves frequently to avoid tearing issue.

### **B) How to Remove Gloves:**

- The gloves should be discarded with an appropriate waste disposal container after use according to local disposal regulations

### **DURATION OF USE:**

Duration of Use is transient (Less than 60 minutes)

### **CLINICAL BENEFITS:**

- 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

### **SIDE EFFECTS:**

Latex Allergy, Powder allergy, Rashes, Itching, Peeling of skin, Hypersensitivity type-I reaction, skin redness, ulcerated skin.

### **RESIDUAL RISK:**















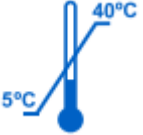


- Anaphylaxis
- Infection
- Inflammation

### **DEVICE PACKAGING CONTAINS:**

Latex Examination Gloves Powdered	100 pcs
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**Latex Examination Gloves-Powdered**

**SYMBOLS USED IN DEVICE SINGLE UNIT PACKAGING AND SALES PACKAGING**

	Manufacturer		Date of Manufacture		Keep away from Sunlight
	Authorized Representative in the European Community/ Authorized representative European Union		Use by Date/ Expiry Date		Keep Dry
	Contains presence of Natural Rubber Latex		Lot. No.		Do not Re-use / Use only once
	CE Mark Symbol		Do not use if package is damaged and consult instructions for use		Caution
	Medical Device		No: of gloves in the package		Storage Temperature
	Unique Device Identifier		Non sterile		

**Notice:**

In case of any serious incident that has occurred in relation to the device, contact manufacturer (MRK Healthcare Pvt Ltd) or authorized representative and competent authority of the member state where user/ patient is established without any delay or within 24 hrs.

**Latex Examination Gloves-Powdered**



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Authorized EU REP

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**Revision History**

Rev. No.	Date	Reason for Revision
A	25/05/2023	Initial Release