

**Latex Surgical Gloves, Non-Sterile Powdered**

**DEVICE INTENDED USE:**

The surgical gloves are intended to act as a protective barrier between the patient and health care worker during invasive surgeries and also to facilitate general hand hygiene.

**DEVICE CATALOGUE NO.:**

| Variants                        | Non-Sterile | Brand Name |
|---------------------------------|-------------|------------|
| Latex Surgical Gloves           | SRGLPN      | NULIFE     |
| Elbow length Gynaecology gloves | ELGLPN      |            |
| Double pair gloves (High risk)  | DPGLPN      |            |
| Under gloves                    | SUGLPN      |            |
| Microsurgery Gloves             | MICLPN      |            |
| Orthopaedic gloves              | ORTLPN      |            |
| Ultra gloves Beaded             | ULTLPNBD    |            |
| Ultra Gloves Beadles            | ULTLPNBL    |            |

**DEVICE SIZES:**

| Variants                        | Sizes  |
|---------------------------------|--|
| Latex Surgical Gloves           | 5.5,6.0,6.5,7.0,7.5,8.0,8.5,9.0  |
| Elbow length Gynaecology gloves | 6.5, 7.5, 8.5  |
| Double pair gloves (High risk)  | Inner:6.0,6.5,7.0,7.5,8.0,8.5, 9.0<br>Outer: 5.5,6.0,6.5,7.0,7.5,8.0,8.5 |
| Under gloves                    | 5.5,6.0,6.5,7.0,7.5,8.0,8.5,9.0  |
| Microsurgery Gloves             | 5.5,6.0,6.5,7.0,7.5,8.0,8.5,9.0  |
| Orthopaedic gloves              | 5.5,6.0,6.5,7.0,7.5,8.0,8.5,9.0  |
| Ultra gloves Beaded             | 5.5,6.0,6.5,7.0,7.5,8.0,8.5,9.0  |
| Ultra Gloves Beadless           | 5.5,6.0,6.5,7.0,7.5,8.0,8.5,9.0  |

**BASIC UDI:**

8905159SRGLPWCB

## **Latex Surgical Gloves, Non-Sterile Powdered**

### **DEVICE DESCRIPTION:**

#### Latex Surgical Gloves – Non-Sterile (Powdered Gloves)

Latex Surgical gloves are Non-Sterile anatomically shaped medical gloves with the thumb positioned towards the palmer surface of the index finger rather than lying flat. These gloves are Pre-powdered. The surgical gloves are intended for use in invasive surgeries.

#### Elbow length Gynaecology Procedure Latex Gloves- Non-Sterile (Powdered Gloves)

Elbow Length gynaecology Gloves anatomically shaped medical gloves with the thumb positioned towards the palmer surface of the index finger rather than lying flat. These gloves are pre-powdered. The Elbow length gynaecology gloves are intended for use various gynecological procedures.

#### Double Pair Gloves (High risk gloves) – Non-Sterile (Powdered Gloves)

The double paired sterile gloves anatomically shaped medical gloves with the thumb positioned towards the palmer surface of the index finger rather than lying flat. The double pair specialty gloves supplied in pair to protect healthcare from contiguous disease. The inner glove is supplied green color compare to outer glove which help user to notice if any perforation on the outer gloves.

#### Under Gloves – Non-Sterile (Powdered Gloves)

Under gloves provide superior feel and natural sensitivity to the finger tips.

#### Microsurgery Gloves – Non-Sterile (Powdered Gloves)

Microsurgery gloves provide superior feel and natural sensitivity to the fingertips during microsurgery. The microsurgery gloves are intended for micro surgery like ophthalmic surgeries.

#### Orthopaedic Gloves – Non-Sterile (Powdered Gloves)

Orthopaedic gloves anatomically shaped medical gloves with the thumb positioned towards the palmer surface of the index finger rather than lying flat. Its brown colour gloves. These gloves are intended for orthopaedic surgery.

#### Ultra Gloves Beaded – Non-Sterile (Powdered Gloves)

Ultra Gloves anatomically shaped medical gloves with the thumb positioned towards the palmer surface of the index finger rather than lying flat and Intended for surgery.

#### Ultra Gloves Beadless – Non- Sterile (Powdered Gloves)

Ultra Gloves anatomically shaped medical gloves with the thumb positioned towards the palmer surface of the index finger rather than lying flat and Intended for surgery.

### **INTENDED USER:**

This is used by surgeons, operation theatre staff and healthcare professional

### **TARGET PATIENT POPULATION:**

Used for all patient population except in patients with known allergy to natural latex rubber.

|          |          |           |           |         |                   |             |             |   |
|----------|----------|-----------|-----------|---------|-------------------|-------------|-------------|---|
| Rev. No. | <b>A</b> | Rev. Date | 24-6-2022 | Doc No: | MRK/IFU/SRG-PD/NS | Page 2 of 6 | Device Name | Latex Surgical Gloves, Non-Sterile Powdered |
|----------|----------|-----------|-----------|---------|-------------------|-------------|-------------|---|



MRK HEALTHCARE PVT. LTD.

ELECTRONIC IFU

## Latex Surgical Gloves, Non-Sterile Powdered

### **DEVICE SHELF LIFE:**

5 years from the date of manufacture printed on the Product Label

### **STORAGE INSTRUCTION:**

It is recommended to store the gloves in dry place, in the temperature of 5°C to 40°C and to protect them against direct sunlight.

### **METHOD OF STERILIZATION:**

Supplied non sterile, suggested to be sterilized using Ethylene oxide before using.

### **INDICATIONS:**

Intended to be worn on the hands during medical surgical procedures to provide barrier against potentially infectious fluids and other contaminants.

### **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.
3. The supplied gloves are non-sterile and suggested to be sterilized using EO before use.
4. 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.
5. Latex gloves are made of Natural rubber latex, which may cause allergic reactions including Latex Allergy – Anaphylactic if the user is allergic to latex.
6. Single Use Packaging label and Sales Packaging Label.
7. Device should not be stored in direct sunlight

### **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.
3. Gloves contain Natural Latex; persons who are sensitive to Latex should consult a physician before using

### **DIRECTION FOR USE:**

- Select the appropriate size Gloves for the hand.
- Take out the Gloves from the pouch.
- Wear the gloves as left to the Left hand & Right to the Right Hand as denoted on the wallet.
- Must check the date of manufacturing and expiry date before use.
- Adjust the gloves as needed.

|          |   |           |           |         |                   |             |             |   |
|----------|---|-----------|-----------|---------|-------------------|-------------|-------------|---|
| Rev. No. | A | Rev. Date | 24-6-2022 | Doc No: | MRK/IFU/SRG-PD/NS | Page 3 of 6 | Device Name | Latex Surgical Gloves, Non-Sterile Powdered |
|----------|---|-----------|-----------|---------|-------------------|-------------|-------------|---|

**Latex Surgical Gloves, Non-Sterile Powdered**

**A) How to Donning Gloves:**

- Rubbing the hand with alcohol or wash with water
- 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.
- For Double Pair Gloves, first wear the green colour inner glove & then wear the outer glove over it.

**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 short term use (< 24 hours)

**MEDICAL 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, Surgical site infection, Inflammation, Allergy, Pain, Rashes, Itching, Peeling of skin, Hypersensitivity type-I reaction, Skin redness, Ulcerated skin

**RESIDUAL RISK:**

- Anaphylaxis
- Blood-Borne Infection, Post-operative wound infection
- Respiratory tract & Pulmonary diseases
- Inflammation
- Toxic to environment

|          |          |           |           |         |                  |             |             |   |
|----------|----------|-----------|-----------|---------|------------------|-------------|-------------|---|
| Rev. No. | <b>A</b> | Rev. Date | 24-6-2022 | Doc No: | MRK/IFU/SG-PD/NS | Page 4 of 6 | Device Name | Latex Surgical Gloves, Non-Sterile Powdered |
|----------|----------|-----------|-----------|---------|------------------|-------------|-------------|---|

**Latex Surgical Gloves, Non-Sterile Powdered**










**DEVICE SINGLE UNIT PACKAGING (PRIMARY PACK) CONTAINS:**

|                                |   |
|--------------------------------|---|
| All Variants                   | 1 Pair/02 Pcs   |
| Double pair gloves (High risk) | Inner Gloves – 1 Pair /02 Pcs<br>Outer Gloves – 1 Pair/02 Pcs |








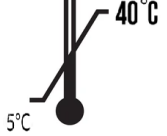
**DEVICE SALES PACKAGING (SECONDARY PACK) CONTAINS:**

| Variants                        | Each Pack Contains |
|---------------------------------|--------------------|
| Latex Surgical Gloves           | 50 Pairs           |
| Elbow length Gynaecology gloves | 25 Pairs           |
| Double pair gloves (High risk)  | 20 Pairs           |
| Under gloves                    | 40 Pairs           |
| Microsurgery Gloves             | 40 Pairs           |
| Orthopaedic gloves              | 40 Pairs           |
| Ultra gloves Beaded             | 40 Pairs           |
| Ultra Gloves Beadles            | 40 Pairs           |

**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   |  | Batch Code               |  | Use only once           |

**Latex Surgical Gloves, Non-Sterile Powdered**

|   |                              |   |   |   |                          |
|---|------------------------------|---|---|---|--------------------------|
|  | No: of gloves in the package |  | Do not use if package is damaged and consult instructions for use |  | Caution                  |
|   |                              |  | Medical Device  |  | Unique Device Identifier |
|  | Non sterile symbol           |  | CE Mark Symbol  |  | Storage Temperature      |

• In case of any adverse event noted, 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



**MRK Healthcare Pvt. Ltd.**

S. No. 153/P& 310, Panch Pippal,

Hansapur, Runi, Unjha-Patan Road, Patan – 384265, Gujarat, India.



Authorized EU REP

**OBELIS S.A**

Bd. Général Wahis, 53

1030 Brussels, Belgium