



## INSTRUCTIONS FOR USE

**GENERAL PRODUCT NAME: LATEX EXAMINATION GLOVES (PRE-POWDERED)**

**BASIC UDI-DI: 89043733LEXGUZ**

**TYPE OF GLOVES – TYPE-I**

**BRANDS: MEDIDCMILE**

**DEVICE CATALOGUE NO.:**

| S. No. | Device Name                          | Brand     | Size        | Catalogue Ref. Number |
|--------|--------------------------------------|-----------|-------------|-----------------------|
| 1      | Latex Examination Gloves, Pre-powder | Medicmile | EXTRA SMALL | LEXG01XS              |
| 2      | Latex Examination Gloves, Pre-powder | Medicmile | SMALL       | LEXG01S               |
| 3      | Latex Examination Gloves, Pre-powder | Medicmile | MEDIUM      | LEXG01M               |
| 4      | Latex Examination Gloves, Pre-powder | Medicmile | LARGE       | LEXG01L               |
| 5      | Latex Examination Gloves, Pre-powder | Medicmile | EXTRA LARGE | LEXG01XL              |

### Intended Use:

It is intended to be worn on the hands, usually in medical examination settings, to provide a barrier against potentially infectious materials, blood & body fluids, substances and saliva and other contaminants. The primary purpose of Examination gloves is to act as a protective barrier to prevent the possible transmission of diseases between healthcare professionals and patients during examination procedures.

### Device Description:

Non-Sterile, Examination Gloves are single use disposable devices made of natural rubber latex that comes in creamy white colour. These gloves may or may not bear powder to facilitate donning. Hand Specific, Beaded Cuff, Smooth Area. Examination Gloves are designed to be perfectly anatomical for comfortable wrinkle-free fitting. The extremely soft rubber reduces finger fatigue and increases efficiency. Low powder content that minimizes skin irritation.

### Caution:

Carefully read all instructions prior to use. Observe all warnings & precautions noted throughout these instructions. Failure to do so may result in complications. To be used by an expert qualified medical professional. The device is for Single Use Only. Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions.

### Patient Population:

All age group Patients (including-Pre-term infants, Neonates, Children, Adolescents, Adults and Old Age).

### User Profile:

Specialists, General Practitioners, Nurses and Patient Caregiver.

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It is intended to be worn on the hands, usually in medical examination settings, to provide a barrier against potentially infectious materials, blood & body fluids, substances and saliva and other contaminants. The primary purpose of Examination gloves is to act as a protective barrier to prevent the possible transmission of diseases between healthcare professionals and patients during examination procedures.

**Contents :**

100 pcs of gloves packed in a dispenser box.

**Size :**

Extra Small, Small, Medium, Large, Extra Large

**Material of Construction :**

Natural Rubber Latex.

**Method of Sterilization :**

Gloves supplied in Non-sterile Condition.

**Duration of Use:**

Duration of Use is transient use (< 60 minutes).

**Shelf Life of the Product:**

3 years from the date of manufacture printed on the Product Label.

**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 have significant greater satisfaction with regard to factors such as quality, safety and durability.
- NRL gloves have high tear propagation strength.
- NRL gloves have high tensile strength.
- NRL gloves have good fit and comfort.

**Care Instructions:**

**Storage:**

It is recommended to store the gloves in dry place, in the temperature of 5-40°C and to protect them against direct sunlight and fluorescent light. If gloves are properly stored, as indicated above, they won't lose their performances and won't change the glove characteristics significantly. If gloves could be affected by ageing or storage, the expiry date is mentioned on the packaging materials.

It is recommended to protect the gloves against humidity. Keep the gloves in a distance of not less than 1m from heating devices, sources of fire and ozone.

**Cleaning:**

The gloves are not designed to be laundered.

**Indications :**

Wearing gloves helps protect both patients and health care workers from infection. When there is a likelihood of coming into direct contact with a patient or patient's blood or other potentially infectious materials (e.g. body fluid, moist body, substances and saliva [in dental procedures]). Defined pathogen barrier as protection from biological agents.

**Contra-indications :**

Allergic patient's or users should not use natural rubber latex, Latex Gloves should not be used in protection from chemicals, radiations protection.

#### **Potential Complications / Risks:**

Dermatological response- Rash, Itch, Hives, Edema, Irritation, Erythema. Non-dermatological response – Dyspnea, Eye Irritation, Nasal Irritation, Wheezing. Diagnostic terms – Allergy (Type-I & IV), Anaphylaxis, Asthma, Contact dermatitis, Rhinitis, Irritant Dermatitis, Urticaria, Tissue Injury.

Itching sensation, respiratory distress, foreign body reaction, latex hypersensitivity. Powder-associated complications including inflammation, allergic reactions and increased risk of infection, contamination and irritation. Pinholes, Thin Spots, Tears, Ripped, Punctured, Exposure to body fluid, Swelling, Microbial penetration of Gloves, Gloves Perforation & etc.

#### **Warnings:**

This device is intended for Single use only. Do Not reuse of the device this may increase the risk of cross contamination due to several aspects including inappropriate reprocessing.

Re-use of single use gloves creates a potential risk for patient or user. It may lead to contamination and / or impairment of functional capability.

Products containing natural rubber latex may cause allergic reactions. Some gloves might contain ingredients which are known to be a possible cause of allergies in sensitised persons, who may develop irritant and/or allergic contact reactions. If allergic reactions should occur, obtain medical advice immediately.

Gloves that are discoloured or stiff may also indicate excessive use or degradation from chemicals. Dispose of gloves when they show any sign of deterioration. Discard the device after single use.

#### **Precautions :**

- (i) Check the integrity of the individual pack of device, before use. Do not use if pack is damaged.
- (ii) This product contains natural rubber latex.
- (iii) Destroy / Dispose the device & its accessories after single use as bio-medical waste as per applicable laws.
- (iv) Do not Re-use. Discard after single use.
- (v) Before usage, inspect the gloves for any defects or imperfections such as holes, pinholes and tears. If the gloves are ripped or punctured during use, dispose of them immediately. If in doubt, do not use the gloves, get a new pair.
- (vi) Contaminated gloves should be cleaned or washed before removal.
- (vii) Ensure the body fluids, blood, chemicals and other infectious materials cannot enter via the cuff.
- (viii) The gloves should not come in contact with a naked flame.
- (ix) Gloves shall not be used for protection against ionising radiation nor for use in containment enclosures.

#### **Adverse Events :**

Dermatological response- Rash, Itch, Hives, Edema, Irritation, Erythema. Non-dermatological response – Dyspnea, Eye Irritation, Nasal Irritation, Wheezing. Diagnostic terms – Allergy (Type-I & IV), Anaphylaxis, Asthma, Contact dermatitis, Rhinitis, Irritant Dermatitis, Urticaria, Tissue Injury.

Powder-associated complications including inflammation, allergic reactions and increased risk of infection, contamination and irritation. Exposure to body fluid, Swelling, Microbial penetration of Gloves, Gloves Perforation & etc.

Allergic manifestations due to natural rubber latex, Surgical Site Infections due to powder content & etc.

#### **Instructions / Measures to be taken in the event of device malfunction or any adverse event:**

- (1) To be used by a qualified medical professional.
- (2) If hands come into contact with a patient's blood or body fluids due to a hole/puncture in gloves during surgery, remove the gloves immediately and wash your hands with soap. To continue the procedures please wear new pair of gloves on your hands.

#### **Use Instructions :**

- (1) Wash up and scrub hands and preferably use examination gloves.
- (2) Dry hands before donning the gloves.
- (3) Gloves need to be donned carefully; do not apply excessive force to pull the gloves when donning.
- (4) Keep the fingernails short and change gloves frequently to avoid tearing issue.
- (5) Always wash hands with soap and water after removing gloves.

**Disposal:**

Used Gloves can be contaminated with contagious or other hazardous substances. They should be disposed as bio-medical waste as per local regulations.

**Adverse Event Reporting:**

In any device malfunction or in case of an adverse event that happened to the user or patient during examination procedure, please report this adverse event to the manufacturer (Swear Healthcare) or authorized representative and competent authority of the member state where user/ patient is established without any delay or within 24 hrs, as per applicable adverse event reporting regulations.

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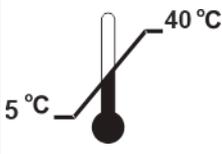
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**SYMBOLS USED IN DEVICE SINGLE UNIT PACKAGING**

|   |   |   |                              |   |   |
|---|---|---|------------------------------|---|---|
|  | Manufacturer  |  | Date of Manufacture          |  | Keep away from Sunlight                   |
|  | Use by Date/ Expiry Date  |  | Keep Dry                     |  | Contains presence of Natural Rubber Latex |
|  | Batch Code  |  | Do not Re-use                |  | Non-sterile                               |
|  | Do not use if package is damaged and consult instructions for use |  | Consult Instructions for Use |  | Caution                                   |

|   |  |   |                     |   |                          |
|---|--|---|---------------------|---|--------------------------|
|  | Storage Temperature  |  | Medical Device      |  | Unique Device Identifier |
|  | Authorized Representative in the European Community/<br>Authorized representative European Union |  | conformity european |   |                          |