PROTEZIONE™
STERILE LATEX SURGICAL GLOVES

LIBERTY MED SUPPLIES PVT. LTD.

- (IND) - Liberty House, Parampuzha P.O, Kottayam, Kerala, India. (Regd. Off)
- (IND) - 7/244A, Ezhacherry, Ramapuram, Kottayam, Kerala, India

91-9061033526, 91-81139 50905
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INSTRUCTIONS FOR USE | **CAT # LMS-001-0101**

Sterile Latex Surgical Gloves | Doc. No: LMS-F-QA-25B [Rev. # 02]

1. Device Description



Sterile Latex Surgical Gloves – Powdered are **single-use sterile gloves made from natural rubber latex** designed for use in surgical procedures to provide an effective barrier against cross contamination between healthcare professionals and patients.

For **powdered gloves**, USP-grade absorbable corn starch is applied as a donning lubricant to facilitate easy donning.

For **powder-free gloves**, a polymer coating is applied to the inner surface of the gloves to facilitate easy donning during surgical procedures, eliminating the need for powder.

Device Variants/models: **Powdered / Powder Free**

PPE Classification: The Sterile latex Surgical Gloves are classified as **Category III Personal Protective Equipment (PPE)** in accordance with **Regulation (EU) 2016/425**. They are intended to protect the wearer against **risks that may cause very serious consequences, such as exposure to hazardous chemicals and infectious agents**, in accordance with their certified performance under **EN ISO 374-1:2016+A1:2018 Type B (KPT)** and **EN ISO 374-5:2016**.

Medical Device Classification: The sterile latex surgical gloves are classified as a **Class IIa Medical Device** in accordance with **Regulation (EU) 2017/745 (EU MDR)**. They are intended for **single use** during **invasive surgical procedures** to provide a sterile barrier that helps protect the patient from microbial contamination and assists in preventing the transmission of infectious agents between the patient and the healthcare professional.

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EU Declaration of Conformity

In accordance with **Article 19 of Regulation (EU) 2017/745 (EU MDR)** and **Article 8 of Regulation (EU) 2016/425 (PPE Regulation)**, the EU Declaration of Conformity for this product is available at:

www.libertymedsupplies.com/DoC

2. Intended Purpose

These gloves are intended to be worn by healthcare professionals during **surgical procedures requiring sterile conditions** to:

- Protect the patient from contamination by the healthcare provider
- Protect the user from exposure to blood and body fluids
- Maintain sterile conditions in surgical environments

Intended Use: The single use sterile latex surgical gloves powdered & powder free are intended to worn on healthcare personal hand, for use in invasive surgical procedures to prevent contamination between healthcare personnel and the patient's body, fluids waste or environment and to be worn once and then discarded. The gloves are designed for transient use.

3. Indications for Use

Sterile Latex Surgical Gloves are indicated for:

- General surgical procedures
- Clinical procedures requiring sterile barrier protection
- Medical examinations where sterile gloves are required

4. Contraindications

Do not use the gloves if:

- The user is known to have **hypersensitivity to natural rubber latex** or **Powder content**
- The package is **damaged or opened**
- The gloves appear **discolored, brittle, or damaged**

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5. Warnings

- This product contains **natural rubber latex & USP garde bio-absorbable corn starch (for powdered gloves only), which may cause allergic reactions including anaphylactic responses** in some individuals.
- For **single use only**.
- **Do not reuse or re-sterilize**.
- Reuse may lead to **loss of barrier integrity and risk of infection**.

6. Precautions

- Choose the **correct glove size** to ensure proper fit and comfort.
- Remove jewellery or sharp objects before wearing gloves.
- Inspect gloves for **defects or damage before use**.
- Replace gloves immediately if **punctured or torn**.
- Avoid prolonged exposure to chemicals.

7. Directions for Use

Step 1 - Preparation

1. Wash, wipe, dry and sanitize hands thoroughly.
2. Select the correct glove size.

Step 2 - Opening the Package

1. Open the sterile glove package using aseptic technique.
2. Avoid touching the external surface of the glove.

Step 3 - Donning Gloves

1. Ensure hands are clean and dry before donning
2. Select gloves of the correct size
3. Pick up the glove by the folded cuff.
4. Insert the hand carefully into the glove.
5. Repeat the procedure for the second glove.
6. For Powdered gloves, please remove excess powder by wiping using a wet sterile towel or other effective validated method prior to use
7. Ensure proper fit on both hands.

Step 4 - During Use

- Avoid contact with sharp instruments.
- Gloves should not be worn beyond the validated duration of use (ie; not recommended for more than 60 minutes)
- The duration of protection depends on the type of exposure and working conditions.
- Replace gloves immediately if damaged, contaminated, or after completion of the intended procedure.

Step 5 - Removing Gloves

1. Grasp the outer surface near the wrist.
2. Peel the glove away turning it inside out.
3. Hold the removed glove in the gloved hand.
4. Slide fingers under the cuff of the remaining glove and remove.

Note: Dispose of the gloves safely after use as per applicable regulations in the user country.

8. Performance Characteristics

The gloves meet the requirements of:

The gloves comply with:

Medical Device Standards

- EN 455-1
- EN 455-2
- EN 455-3
- EN 455-4
- ISO 10282
- ASTM D3577

Test Compliance Performed to meet PPE Standards/ requirements

- EN ISO 21420:2020
- EN ISO 374-1:2016+A1:2018 Type B
- EN ISO 374-2:2019
- EN ISO 374-4:2019
- EN ISO 374-5:2016 / ASTM F1671/F1671 M-22 Viral penetration resistance test
- ISO 16190:2021

- EN 16523-1 (Chemical Permeation Test Method)
- ISO 3071:2020

Chemical Protection

The gloves have been tested according to EN ISO 374-1:2016+A1:2018 and classified as Type B.

Certified Chemical Codes:

- K – Sodium Hydroxide 40%
- P – Hydrogen Peroxide 30%
- T – Formaldehyde 37%

Protection is limited to the chemicals tested and certified.

WARNINGS:

The following precautions shall be considered when using these gloves for protection against chemical risks:

1. *The chemical resistance performance indicated for these gloves does not reflect the actual duration of protection in the workplace or the differences in resistance between mixtures and pure chemicals.*
2. *The chemical resistance has been assessed under laboratory conditions using samples taken from the palm area of the gloves. The results relate only to the chemicals tested. The performance may differ when the chemicals are used in mixtures.*
3. *It is recommended to verify that the gloves are suitable for the intended application, as actual workplace conditions may differ from the type-test conditions, particularly with regard to temperature, abrasion and degradation.*
4. *During use, protective gloves may provide reduced resistance to hazardous chemicals due to changes in their physical properties. Movements, snagging, rubbing and degradation resulting from chemical contact may significantly reduce the actual period of protection. For corrosive chemicals, degradation may be the most important factor to consider when selecting chemical-resistant gloves.*
5. *Before use, inspect the gloves for any visible defects, damage, holes or imperfections. Do not use damaged gloves.*
6. *For single-use gloves: For single use only. Do not reuse.*

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Biological Protection

The gloves comply with EN ISO 374-5:2016.

The glove provide protection against:

- Bacteria
- Fungi
- Viruses

The gloves have been tested for viral penetration according to ASTM F1671/F1671 M-22 Viral penetration resistance test.

WARNINGS:

The following precautions shall be considered when using these gloves for protection against microorganisms:

1. *The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.*
2. *The gloves provide protection against microorganisms (bacteria and fungi) in accordance with the applicable test requirements of EN ISO 374-5:2016.*

General Warning EN ISO 21420:2020 :

1. *Natural Rubber Latex Warning: These gloves contain natural rubber latex, which may cause allergic reactions, including anaphylactic reactions, in sensitised individuals.*
2. *Inspection Before Use: Inspect the gloves for any visible damage, holes, tears or other imperfections before use. Do not use gloves that are damaged or defective.*
3. *Intended Use: Select gloves appropriate for the intended application and the hazards involved. The selection of gloves shall be based on an assessment of the risks present in the workplace.*
4. *Limitations of Protection: The protective performance of the gloves is limited to the hazards and performance levels indicated in the relevant markings and test results. The gloves may not provide protection against hazards for which they have not been tested.*
5. *Storage: Store the gloves in their original packaging in a cool, dry and well-ventilated place. Protect them from direct sunlight, excessive heat, moisture, ozone and other conditions that may adversely affect their performance.*
6. *Single Use: These gloves are intended for single use only. Do not wash, clean, disinfect or reuse them.*

7. *Donning and Doffing: Ensure that hands are clean and dry before donning the gloves. Avoid contact with contaminated external surfaces when removing the gloves. Dispose of used gloves safely and wash hands after removal.*
8. *Disposal: Dispose of used gloves in accordance with the applicable local regulations and the nature of the contamination.*

9. Sterilization

The gloves are sterilized using validated sterilization processes such as:

- Ethylene Oxide (EO) or

Sterility Assurance Level (SAL): 10^{-6}

Note: The product remains sterile unless the packaging is damaged or opened.

10. Storage Conditions

Store gloves under the following conditions:

- Temperature: Storage Temp. 5^{0}C to 30°C
- Protect from direct sunlight
- Protect from Moisture

11. Shelf Life

The shelf life is indicated by the expiry date printed on the packaging.

Expiry Date Claimed : 3 years from the date of Manufacture

Note: Do not use the product after the expiry date.

Shelf life is validated in accordance with EN 455-4 / ASTM D7160-16 requirements.

12. Disposal

Dispose of used gloves according to:

- Hospital infection control protocols
- Applicable biomedical waste regulations of the user country

13. Symbols Used on Label

Symbols comply with ISO 15223-1.

Symbol	Meaning	Explanation
	Manufacturer	**Liberty Med Supplies Pvt. Ltd.** **Regd. Office**: Liberty House, Parampuzha P.O, Kottayam, Kerala-686004 - India **Mnfg. Site**: 7/244 A, Ezhacherry P.O, Ramapuram, Kottayam, Kerala, 686651 - India Customer Care: +91-9061033526, +91-8113950905 info@libertymedsupplies.com, www.libertymedsupplies.com Mnfg. Lic. No. : MFG/MD/2025/000036 Mnfgr. SRN: IN-MF-000019859
EU REP	Authorized representative in the European Community/ European Union)	Bureau Medica Intercert DK Kaj Sommers Vej 6, 3320 Skævinge - Denmark www.bureaumedica.com, info@bureaumedica.com Ph: + 45 91632811 | SRN: DK-AR-000043850
	Date of manufacture	Indicates the date when the medical device was manufactured.
	Use-by date / Expiry Date	Indicates the date after which the medical device is not to be used.
LOT	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Distributor	Indicates the entity distributing the medical device into the locale.
STERILE EO	Sterilized using ethylene oxide]	Indicates a medical device that has been sterilized using ethylene oxide.
	Single sterile barrier system with protective packaging inside	Indicates a single sterile barrier system with protective Packaging inside
	Do not resterilize	Indicates a medical device that is not to be resterilized
	Do not re-use	Indicates a medical device that is intended for one single use only
	Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information

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	Keep away from sunlight	Indicates a medical device that needs protection from light sources
	Keep dry	Indicates a medical device that needs to be protected from moisture
	Upper limit of temperature	Recommended Storage Temperature: Up to 30°C
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use
	Caution	– For single use only. Reuse may result in infection, loss of sterility, or product failure. – Do not resterilize. – Do not use if package is damaged. Sterile until package is opened or damaged. – This product contains natural rubber latex & usp grade bio-absorbable corn starch as donning agent, which may cause allergic reactions in some individuals. In case of any allergic issues, discontinue use and consult a physician. Disposal of Gloves: Gloves are for transient use of up to 60 minutes and must be safely disposed of afterward as per applicable regulations of the user country.
	Contains or presence of natural rubber latex	Indicates the presence of dry natural rubber or natural rubber latex as a material of construction within the medical device or the packaging of a medical device
	Medical device	Indicates the item is a medical device
	Unique device identifier	Indicates a carrier that contains unique device identifier information. The Unique Device Identifier (UDI) is provided on the packaging
	CE Mark	A CE Mark is a symbol that must be affixed to many products before they can be sold on the European market.

PPE REGULATION (EU) 2016/425 – LABELLING		
	CE Mark as per PPE	A CE Mark is a symbol that must be affixed to many products before they can be sold on the European market. Notified Body Details: SGS Fimko Oy Takomotie 8, FI-00380 Helsinki, Finland Notified Body No.: 0598
	Protective gloves against dangerous chemicals and micro-organisms	Protective gloves against dangerous chemicals and micro-organisms Part 5: Terminology and performance requirements for micro-organisms risks

EN 374-1:2016 TYPE B KPT	Permeation resistance against chemicals	'Type B' gloves, achieved level 2 or greater against at least three of the chemicals listed in EN ISO 374-1

14. UDI Information

Where applicable, the device label may contain **Unique Device Identification (UDI)** information including:

- UDI-DI (Device Identifier)
- UDI-PI (Production Identifier such as lot number and expiry date)

UDI requirements are applicable for regulatory markets that mandate device traceability.

15. Declaration of Conformity

The EU Declaration of Conformity (DoC) is available on our official website (www.libertymedsupplies.com).

The End users can access and download the applicable Declaration of Conformity by scanning the QR code provided on the product packaging for reference and regulatory information.

- Declaration of Conformity document Ref. # LMS-PPE-TF-01-DOC-01

16. Manufacturer Information & EU Representative

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Mnfg. Lic. No. : MFG/MD/2025/000036 | SRN: IN-MF-000019859
An ISO 13485:2016 | ISO 9001:2015 | ISO 14001:2015 | ISO 45001:2018
Sedex | ZeD Gold | BIS Certified Company

"This IFU is publicly available on our company website: www.libertymedsupplies.com.
OR
Scan the QR code provided on the product labelling to access further information."