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
info@libertymedsupplies.com | www.libertymedsupplies.com

INSTRUCTIONS FOR USE | **CAT # LMS-001-0101**

Sterile Latex Surgical Gloves – Powdered

Doc. No: LMS-F-QA-25B [Rev. # 01]

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.

The gloves are **pre-powdered** using USP grade bio-absorbable corn starch, **anatomically shaped**, and designed to provide **high tactile sensitivity, flexibility, and grip**.

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

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**

5. Warnings

- This product contains **natural rubber latex & USP garde bio-absorbable corn startch, 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**.

- Surgical latex gloves are not puncture-proof; take care when handling sharp instruments.
- Prolonged exposure to natural rubber latex can lead to sensitivity or allergic reactions in some individuals.
- Check the expiry date before use; do not use after the expiry date.
- Check the packaging for physical damage before use; do not use if the package is opened or damaged.

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**.
- Ensure proper fit to minimise the risk of tears or perforations.
- Wearing gloves does not ensure complete protection against contamination; good medical practice and hand hygiene before and after use of the gloves are always recommended.
- Avoid prolonged continuous wear; change gloves at appropriate intervals and replace immediately if glove integrity is in doubt.
- After donning, remove residual powder by wiping the gloves with a wet sterile towel.
- Available sizes: 6.0, 6.5, 7.0, 7.5, 8.0, 8.5 and 9.0 (glove length 270–480 mm). Select the size matching the user's hand to ensure proper fit; follow the recommended donning and doffing procedures (see Directions for Use).

Adverse Events / Undesirable Side Effects

The following residual risks and undesirable side-effects may be associated with the use of the device:

– Type I (immediate) hypersensitivity to natural rubber latex proteins, ranging from localised urticaria to systemic anaphylactic reaction.
– Skin irritation, dryness or localised reaction.
– Infection risk if the sterile barrier is compromised (pack damaged or opened) or if the single-use device is reused or re-sterilized.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer (info@libertymedsupplies.com) and to the competent authority of the Member State in which the user and/or patient is established.

Packaging and Quantity

The device is supplied sterile. Each sterile peel-open pouch contains one pair (two gloves). The dispenser box contains 50 pairs (100 gloves). Shipper cartons contain multiple dispenser boxes as stated on the outer (tertiary) label. Where the label states contents/quantity “per pack”, this refers to the number of pairs in the immediate dispenser box.

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. Pick up the glove by the folded cuff.
2. Insert the hand carefully into the glove.
3. Repeat the procedure for the second glove.
4. Remove excess powder by wiping using a wet sterile towel or other effective validated method prior to use
5. Ensure proper fit on both hands

Step 4 - During Use

- Avoid contact with sharp instruments.
- Replace gloves if punctured or contaminated.

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:

EN 455-1 | EN 455-2 | EN 455-3 | EN 455-4 | ASTM D3577 | IS 13422 | ISO 10282 Standards

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	Indicates a single sterile barrier system with protective Packaging inside

	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
	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	Consult IFU for important safety information
	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.

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. Manufacturer Information & EU Representative

EU REP

Bureau Medica Intercert DK
Kaj Sommers Vej 6, 3320 Skævinge - Denmark
www.bureaumedica.com, info@bureaumedica.com
Ph: + 45 91632811 | SRN: DK-AR-000043850

Manufactured by:

Liberty Med Supplies Pvt. Ltd.
Liberty House, Parampuzha P.O, Kottayam, Kerala-686004 - India
7/244 A, Ezhacherry P.O, Ramapuram, Kottayam, Kerala, 686651 - India
Ph: +91-8113950905, Customer Care: +91-9061033526
info@libertymedsupplies.com | www.libertymedsupplies.com

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

Revision history: R1 (21-Jul-2026) — Added 'Adverse Events / Undesirable Side Effects', added 'Packaging and Quantity' clarification for 'per pack' , intended purpose confirmed consistent with the Technical File. Storage range (5–30°C) retained. Aligned the IFU with all information-for-safety risk controls in the Risk file (RMS-R1) and the warnings/precautions in the CER: added 'not puncture-proof / sharps care', expiry & package-damage checks, prolonged-latex-exposure warning; added hand-hygiene (before & after), proper-fit, wear-duration/change, powder wipe-off & avoid-wound-contact precautions, and a glove sizing guide.