

Primus Gloves Private Limited		
Latex Examination Gloves- Powder Free		
Instruction for Use		
Doc No: PGPL/IFU/LEG PF	Rev No: 01	Date: 03.08.2023

Instruction for Use

1. Device Name

Latex Examination Gloves- Powder Free

2. Model/Variant and Brand Name

	Model/Variant Name	Brand Name
1.	Regular Cuff	Protac
2.	Long Cuff	Protac

3. Device Description:

The Latex Examination Gloves – Powder Free are made of natural rubber latex. The Latex Examination Gloves – Powder Free are sterile and disposable medical gloves. These are intended to use by healthcare professionals during medical procedures to help prevent cross-contamination between caregivers and patients. The Latex Examination Gloves – Powder Free are having precise sizing with better precision and complies as per the standards ASTM D 3578-19 and EN 455. The Latex Examination Gloves – Powder Free are sterilized by Ethylene Oxide or Gamma Irradiation as per the customer requirement.

4. Device Sizes

#	Variant Name	Variant Details
1.	Regular Cuff	Size – XS, S, M, L, XL Length- 240 mm
2.	Long Cuff	Size – XS, S, M, L, XL Length- 280-500 mm

5. Basic UDI-DI

Basic UDI-DI - 89060124501002H

6. Device Intended Use

Intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

7. Duration of Use

Duration of Use is Transient use (< 60 minutes)

8. Device Intended User

Doctors, nurses, caregivers, dentists and other healthcare workers use the Examination gloves.

9. Target Patient Population

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

10. Operating Instructions:

- 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 as left to the Left hand & Right to the Right Hand as denoted on the pouch.
- Must check the date of manufacturing and expiry date before using
- Adjust the gloves as needed.

11. Precautions & Warnings:

- The product should be protected from light sources, in particular direct sunlight or intense artificial light having high ultra-violet content.
- Do not Re-sterilize – The excess ETO residue which stays after re-sterilization may be toxic to the users and patients and Gamma re-sterilization can leads to loss of glove property.

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

12. Medical 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 sterile work area during aseptic duties
- Protection from chemicals
- Defined pathogen barrier as protection from biological agents.

13. Contraindications

- Gloves are made of Natural rubber latex, which may cause allergic reactions including Latex Allergy – Anaphylactic if the user is allergic to latex.

14. Side Effects/Adverse Events

- Latex Allergy, Inflammation, Allergy, Pain, Rashes, Itching, Peeling of skin, Hypersensitivity type-I reaction, Skin redness, Ulcerated skin

15. Residual Risks

- Infection, Anaphylaxis (Latex Allergy)

16. Clinical Benefits

- Gloves are competent barrier to protect against infections for both healthcare professionals and the patients.
- Gloves provide lower rates of perforation and lower viral leakage rates.
- Gloves are easy to put on comfortable to wear and provide adequate, durable protection.
- Gloves have good barrier integrity.
- Gloves have less after-use defects.
- Gloves has significant greater satisfaction with regard to factors such as quality, safety and durability.
- Gloves have high tear propagation strength
- Gloves have low perforation rate
- Gloves have high tensile strength
- Gloves have good fit and comfort

17. Method of Sterilization

The method of Sterilization is EO Gas or Gamma Radiation as customer demands

18. Disposal instructions:

- Gloves after usage remove gently & carefully.
- Discard as per the Statutory & regulations laws.

19. How Gloves are Supplied:

- The Colour of the gloves Creamy White.
- Gloves are supplied as a pair in each unit of packing.
- IFU is shared per gloves package

20. Storage Conditions:

Prolonged storage of gloves should be in between 10 - 25°C.

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21. Explanation of symbols used on label



Do not Re-sterilize



Do not use if package is Damaged



Instructions for Use



Expiry Date



Sterilized using Ethylene Oxide



Sterilized using Gamma Irradiation



Do not Reuse



Latex



Material should be protected from oxidation



Keep Away from Sunlight



Size



Lot Number



Date of Manufacture



Keep Dry



Storage Condition



CE Logo



Unique Device Identification



One pair



Sterile Barrier System



Medical Device

Manufacturer



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22. Manufacturer License Number and GTIN Number

Manufacturer License Number: No.9/01/1998:IL:CSEZ/2676

GTIN No: 890601245

23. Revision History

Revision No	Changes Incorporated	Effective Date
00	Initial Release	07.04.2022
01	Updated section 11, 19 and 21 and added section 22 as per TR1 comments	03.08.2023