Instruction for Use

1. Device Name

Latex Surgical gloves- Powder Free

2. Model/Variant and Brand Name

Model/Variant Name	Brand Name
Regular Cuff	Protac, Novicare, KBM, Krivicare, Protex, Maxens, Precinium, Protac Polymer coated
Orthopaedic	Protac Protex
Ophthalmic	Protac
Long Cuff/Gynaecological	Protac, Surgilac, Sterix, Euromedis

3. Device Description:

The Latex Surgical Gloves – Powder Free are made of natural rubber latex. The Latex Surgical 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 Surgical Gloves – Powder Free are more precise sizing with better precision and complies as per the standards ASTM D3577-19 and EN 455. The Latex Surgical Gloves – Powder Free are sterilized by Ethylene Oxide or Gamma Irradiation as per the customer requirement. These gloves can be used in gynaecological surgeries or procedures.

4. Device Sizes

#	Variant Name	Variant Details
i.	Regular Cuff	Size- 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 Length- 290 mm
ii.	Orthopaedic	Size- 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 Length- 285 mm
iii.	Ophthalmic	Size- 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 Length- 285 mm
iv.	Long Cuff / Gynaecological	Size- 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 Length- 350-500 mm

5. Unique Device Identification (UDI)

Basic UDI-DI - 89060124501002C

6. Device Intended Use

Latex Surgical Gloves Powder Free is a Disposable Device Intended for medical purpose that is worn by operating/procedure room personnel to protect surgical wound/Personnel and to protect the personnel performing the Operation/Procedure from contamination. These gloves can be used in gynaecological surgeries or procedures.

7. Duration of Use

Duration of Use is Transient use (< 60 minutes). If it exceeds, there is a high chance for glove perforation which may cause surgical site infections. User should change the gloves hourly once.

8. Device Intended User

Healthcare Surgeons, Operation Theatre Personnel and Healthcare providers for the patients at high risk of infections.

9. Target Patient Population

These sterile latex gloves are 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.
- 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.
- Do not use if the pouch is torn or sterility is compromised.
- 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 the surgical Site during surgery.
- Defined pathogen barrier as protection from biological agents.

13. Contraindications

- Latex gloves are made of Natural rubber latex, which might cause allergic reactions if the user is allergic to latex.

14. Side Effects/Adverse Events

Latex Allergy, Surgical site infection, 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

- 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

17. Method of Sterilization

The method of Sterilization is Ethylene Oxide and Gamma Radiation as per the customer requirement.

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.

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 7, 11, 19 and 21 and added section 22 as per TR1 comments	29.08.2022
02	Updated section 11	01.03.2023