STERILE LATEX SURGICAL GLOVES POWDERED

(STERILE POWDERED -TYPE 1}

DESCRIPTION:

1. **Material**:- These gloves are primarily composed of natural rubber latex (Type1).
2. **Powder-**: US FDA approved USP grade Bio-absorbable cornstarch and Powder content is < 15 mg/dm2.
3. **Color**: The gloves are creamy white to pale yellow in color, which is the natural color of latex.
4. **Cleanliness**: They are free from various contaminants like dirt marks, oil stains, embedded foreign particles, and coagulum, ensuring a clean product.
5. **Sterilization**: The gloves are ethylene oxide (EO) sterilized, which is a common method to ensure sterility in medical equipment.
6. **Conformance to Standards**: These gloves conform to various standard specifications, including IS 13422:1992, ASTM D 3577:2019, EN 455-1:2020, EN 455-2:2009+A2:2013, EN 455-3:2006, and EN 455-4:2009. This means they meet the quality and safety requirements specified in these standards.

These gloves are suitable for medical and surgical use, providing a high level of cleanliness and sterility, which is crucial in healthcare settings to prevent infections and ensure the safety of both patients and healthcare workers.

DESIGN & FEATURES:

1. **Anatomical Shape**: The gloves are anatomically shaped, with the thumb positioned towards the palmar surface of the index finger rather than lying flat. This design provides a better fit and comfort for the wearer.
2. **Cuff**: The cuff of the gloves is designed to fit closely without being constrictive. It should not roll back or ruckle while in use, ensuring a secure fit.
3. **Material Properties**: The physical properties, dimensions, and tensile strength of the material meet European CE/USFDA standards, including EN 455, ASTM D 3577, and IS 13422. This ensures the gloves meet the required quality and safety standards.
4. **Micro Rough Surface**: The inner palm and inner part of the finger area have a micro-rough surface, which provides a good grip at the wrist and in curved fingers. This feature is important for maintaining dexterity and control during medical procedures.

5. **Shelf-Life**: The gloves have a shelf-life of 5 years from the date of manufacturing. This indicates their long-term usability and durability when stored properly.
6. **Chemical Residue**: Each glove has non-detectable levels of chemical residue, ensuring that they are free from harmful chemicals that could potentially harm the wearer or patients.
7. **Sterilization**: The gloves are sterilized by a validated process cycle, conforming to ISO 11135:2014 standards. This ensures that the gloves are free from harmful microorganisms.
8. **Viral Penetration Test**: The gloves pass the viral penetration test as per ASTM F 1671. This means they provide a barrier against viruses and other microorganisms.
9. **Sterility Assurance Level (SAL)**: The gloves have a Sterility Assurance Level of 10^-6, indicating an extremely high level of sterility.
10. **Biocompatibility**: The gloves are biologically compatible as per ISO 10993-Part 5, 7, 10, and 11, which means they are designed not to cause adverse biological reactions when in contact with the skin.
11. **Non-Toxic and Non-Irritant**: The gloves are non-toxic and non-irritant, ensuring they are safe for use on the skin without causing irritation or harm.

These features make these gloves suitable for medical and surgical applications, where a high level of safety, comfort, and sterility is required. They are designed to meet stringent standards and provide protection for both healthcare workers and patients.

INTDENDED USE:

These gloves are specifically designed for use in surgical work. They are meant to be worn once and then discarded after use. Surgeons and healthcare personnel wear these gloves on their hands to prevent cross-contamination between themselves and the patient's body, bodily fluids, waste, or the surrounding environment. The primary purpose of these gloves is to maintain a sterile barrier during surgical procedures and to ensure the safety and hygiene of both healthcare personnel and patients. These gloves are intended for transient use and are meant to be used in conjunction with invasive surgical procedures where maintaining a sterile environment is of utmost importance.

GENERAL INSTRUCTIONS:

1 Store the gloves in a cool, dry place, and keep them away from direct sunlight to maintain their integrity.

2 These gloves are sterile and intended for single use only. They remain sterile until the package is opened or damaged.

3 They are designed for transient use, typically for procedures lasting less than 60 minutes.

4 Note that this product contains natural rubber latex, which can potentially cause allergic reactions, including severe anaphylactic responses in some individuals. Users should be aware of latex allergies.

5 Reusing gloves is strongly discouraged as it can lead to the risk of infection, allergic reactions, and diminished barrier protection. Disposable gloves are meant for single use to maintain a high level of hygiene and safety**.**

6 It is important to follow proper disposal procedures for these gloves, which should align with hospital policies or the regulatory norms of your country. Proper disposal helps prevent the spread of infections and ensures environmental responsibility. Therefore, after using these gloves, dispose of them in accordance with the guidelines and regulations set by the hospital or the relevant authorities in your country.

PHYSICAL DIMENSION (ASTM D 3577: 2019, EN 455-2:2009+A2:2013, IS: 13422:1992)

Size	Length (mm)	Palm Width (mm)	**Thickness (in mm)**					
			Cuff (Min)		Palm (Min)		Finger (Min)	
	Min	Specification	Standard	One Glove	Standard	**One Glove**	Standard	**One Glove**
5½	250	70 ± 6	0.10	0.11	0.10	0.14	0.10	0.16
6	265	76 ± 6						
6½		83 ± 6						
7	270	89 ± 6						
7½		95 ± 6						
8		102±6						
8½	280	108±6						
9		114 ± 6						

PHYSICAL PROPERTIES:

Characteristics	Before Ageing	After Ageing 70 ± 2° C for 168 hrs.
ASTM D 3577:2019, IS 13422:1992		
Tensile Strength (Mpa) min.	24	18
Ultimate Elongation(%) min.	750	560
Stress at 500% Elongation (Mpa) Max.	5.5	NA

EN 455-2:2009+A2:2013		
Minimum force at break	9.0 N	9.0 **N**

Aqueous extractable protein content **(As per standards ASTM D 3577:2019)**	< 200 µg/dm^2 -Test method ASTM D 5712-15 (2020)
Powder content **(As per standards ASTM D 3577:2019)**	< 15 mg/dm2 -Test method ASTM D 6124-06 (2017)
Sterilization	Ethylene Oxide
Sterility	Shall pass Sterility test as per IP /USP/ EU Pharmacopeia
Labeling	Shall comply with government, regulatory and customer requirements
Packing Packing type: • 1 Pair (1 left and 1 right) of gloves per inner wrapper. • 1 inner wrapper per pouch. • 50 pouches per inner (dispenser) box. 500 pairs in an outer carton	Shall comply with standard packing and customer requirements