NON-STERILE LATEX EXAMINATION GLOVES –Powdered (TYPE 1)

DESCRIPTION:

1. Color: Creamy white in color. This coloration is typical for latex gloves.
2. Material: The gloves are primarily made from natural rubber latex (Type-1). Natural rubber latex is a material derived from the sap of rubber trees and is known for its elasticity and comfort.
3. Cleanliness: They are free from various impurities such as dirt marks, oil stains, embedded foreign particles, and coagulum. This ensures a higher level of cleanliness and reduces the risk of contamination during use.
4. Texture: The gloves are textured at the fingertip area. Texture can enhance grip and tactile sensitivity, making it easier to handle objects and perform delicate procedures.

These specifications are common characteristics found in certain types of latex examination gloves, particularly those designed for medical use or other applications where cleanliness and tactile sensitivity are crucial factors.

DESIGN & FEATURES:

1. Standards Met: The gloves meet various standards, including EN 455-1:2000, EN 455-2:2009+A2:2013, EN 455-3:2006, EN 455-4:2009, and ASTM D 3578:2019. These standards ensure that the gloves comply with specific quality, safety, and performance criteria set by regulatory bodies or organizations.
2. Ambidextrous Fit: The gloves are designed to fit either hand (ambidextrous), allowing ease of use without the need to differentiate between left and right-handed gloves.
3. Powder: They are lightly powdered with modified absorbable corn starch of USP grade. This powder facilitates easy donning and removal of the gloves and helps absorb moisture for enhanced comfort during prolonged wear.
4. Cuff Design: The cuff is designed to fit snugly without constricting the wrist. It is also specified not to roll back or ruckle during use, ensuring a secure and comfortable fit.
5. Shelf Life: The gloves have a shelf life of 5 years from the date of manufacturing, indicating the duration within which they are expected to maintain their integrity and quality if stored properly.
6. Chemical Residue: Each glove has non-detectable levels of chemical residue. This feature ensures that the gloves are clean and free from residual chemicals that might otherwise cause irritation or pose health risks.
7. Non-Toxic and Non-Irritant: The gloves are specified as non-toxic and non-irritant, emphasizing their safety for use and minimizing the risk of adverse reactions or irritations for the wearer.

These features collectively define the quality, safety, and usability aspects of the gloves, aligning with various industry standards and ensuring their suitability for medical examinations and other applications requiring protective handwear.

CAUTION:

1. Storage: Store the gloves in a cool, dry place, and keep them away from direct sunlight. Proper storage helps maintain the integrity and quality of the gloves.
2. Latex Allergy Warning: These gloves contain natural rubber latex, which can potentially cause allergic reactions in some individuals. If you experience any symptoms of a latex allergy (such as skin irritation, redness, itching, or difficulty breathing), discontinue use immediately and seek medical advice from a physician.
3. Removing Powder: After putting on the gloves, it's advised to remove the powder by wiping the gloves thoroughly with a sterile wet sponge, sterile wet towel, or using another effective method. This step helps reduce potential irritation or discomfort caused by the powder.
4. Glove Reuse Warning: Reusing gloves is strongly discouraged due to various risks. Reusing gloves can lead to increased chances of infection transmission, reduced barrier protection due to wear and tear, and heightened risk of allergic reactions. Proper disposal and using a new pair of gloves for each new task or patient interaction are recommended to maintain hygiene and safety standards.

Following these cautionary instructions is essential to ensure the safe and effective use of the gloves, minimize potential allergic reactions, and maintain a higher level of protection for both the wearer and individuals in contact with the wearer during various procedures or tasks.

INTENDED USE

1. Protaction Against Cross-Contamination: These gloves are designed to provide a protective barrier between the user and patients or potentially contaminated materials. They aim to minimize the risk of cross-contamination between the wearer and patients, as well as between different patients during medical procedures.
2. Medical Examinations: The gloves are intended for use during medical examinations, which may include physical examinations, routine check-ups, or other assessments performed by healthcare professionals.
3. Diagnostic Procedures: They are suitable for use during diagnostic procedures, such as blood tests, specimen collection, or other tests where a barrier between the healthcare provider and the patient is necessary.
4. Therapeutic Procedures: During various therapeutic procedures, these gloves can be utilized to protect both the healthcare provider and the patient from

potential contamination or exposure to bodily fluids or other hazardous materials.

5. Handling Contaminated Medical Materials: These gloves are appropriate for handling contaminated medical materials, including waste disposal, handling infectious substances, or any materials that might pose a risk of transmission of infectious agents.

The primary goal of these gloves is to ensure the safety of both the healthcare provider and the patients by preventing the spread of infections, maintaining hygiene standards, and reducing the risk of cross-contamination in medical settings.

Physical Dimension as per – EN 455-2: 2009+ A2 ; 2013 , ASTM D 3578:2019

Size	Length (mm)Min	Palm Width (mm)	Thickness (mm) Min	
			Palm	Finger
Extra small	≥240	≤80	0.08	0.08
Small		80±10		
Medium		95±10		
Large		110±10		
Extra large		≥110		

Physical Properties as per EN 455-2 : 2009+ A2 ; 2013

Characteristics	Before Ageing	After Ageing 70 ± 2° C for 168 hrs.
Force at break	≥ 6 N min	≥ 6 N min

Total protein content (**as per EN 455-3:2006**) : < 200 µg/ dm^2 Powder content (**as per EN 455**

Physical properties as per ASTM D 3578:2019

Characteristics	Before Ageing	After Ageing 70 ± 2° C for 166 hrs ± 2hrs.
Tensile strength (MPa) ,Min	18	14
Ultimate elongation (%) ,Min	650	500
Stress at 500% (Mpa) , Max	5.5	NA
Characteristics	Before Ageing	After Ageing 70 2 C for 166 hrs ± 2hrs.
Tensile strength (MPa) ,Min	18	14
Ultimate elongation (%) ,Min	650	500
Stress at 500% (Mpa) , Max	5.5	NA

Total protein content (**as per ASTM D 3578:2019**) : < 200 µg/dm^2

Powder content (**as per ASTM D 3578:2019**) : < 10 mg/dm^2

Packing & Labeling : Shall comply with the regulatory requirements and Customer requirements

PERFORMANCE REQUIREMENTS

Sampling procedure: ISO 2859 Part I Sampling plan
i. General Inspection Level (For freedom from pinholes)
ii. Special Inspection Level (For all other tests)

Characteristic	**Inspection Level**	**AQL**
Freedom from holes (**ASTM D 3578:2019**)	G1	2.5
Freedom from holes (**EN 455-1:2000**)	G1	1.5
Physical Dimensions	S2	4.0
Physical Properties	S2	4.0
Extractable Protein Content	N=3	N/A
Powder Content	N=2	N/A
Labelling	S2	1.5
Packing	S2	1.5