

Summary of IS 13422 : 2024 (Single-Use Sterile Rubber Surgical Gloves — Specification)

IS 13422:2024, harmonized with **ISO 10282:2023**, specifies the requirements for single-use sterile rubber surgical gloves. These gloves are designed for use in surgical procedures, providing a protective barrier to prevent cross-contamination between patients and healthcare providers. They are intended for single use, with options for smooth or textured surfaces and available in both natural and synthetic rubber materials.

Consumers, including healthcare professionals, expect these gloves to meet the highest standards of safety, comfort, and reliability. Key quality parameters include:

- **Durability:** High tensile strength and resistance to tearing, even during rigorous surgical procedures.
- **Watertightness:** Assurance that the gloves are free of leaks to maintain sterility and protection.
- **Sterility:** Compliance with sterilization standards to prevent infections.
- **Comfort and Fit:** Anatomical design with appropriate sizes to minimize hand fatigue during extended use.
- **Hypoallergenic Materials:** Non-toxic compounds and low allergenic potential, particularly for individuals sensitive to latex.

IS 13422:2024 provides a structured framework to ensure surgical gloves meet these quality expectations:

1. **Performance Requirements:** Specifies dimensions, tensile properties, and watertightness tests to ensure durability and reliability.
2. **Material Safety:** Mandates compliance with ISO 10993 for biocompatibility, ensuring non-toxic and hypoallergenic materials.
3. **Sterility and Hygiene:** Requires gloves to be sterilized and packaged to maintain integrity, with clear labeling to identify their sterility status.
4. **Sampling and Testing:** Defines stringent quality control measures, including sampling plans (ISO 2859-1) and acceptance quality limits (AQLs), to ensure consistency.
5. **Marking and Packaging:** Ensures clear labeling for size, material, and warnings, while robust packaging preserves the product's quality during storage and transport.