

IS/IEC 80601-2-58 : 2016 -Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 58 Lens removal devices and vitrectomy devices for ophthalmic surgery

The Indian Standard **IS/IEC 80601-2-58 : 2016**, aligned with the international IEC standard defines the safety and performance requirements for Lens Removal Devices and Vitrectomy Devices used in ophthalmic surgery. This includes equipment consoles, surgical handpieces, and accessories. The standard aims to ensure these devices are safe and effective for both patients and medical professionals.

Consumers, including patients and medical professionals, expect these devices to be accurate, reliable, and safe. Key quality parameters include: accurate irrigation and aspiration pressure, precise diathermy power and frequency, safe and effective illumination output, controlled lens fragmentation, and a reliable vitrectomy probe cut rate. Additionally, consumers expect clear instructions for use, including information on priming, cleaning, disinfection, sterilization, and maintenance procedures.

The standard addresses these expectations by establishing specific requirements and test methods for each quality parameter. It defines acceptable limits for hazardous outputs such as irrigation pressure, aspiration vacuum, diathermy power, and illumination intensity. The standard outlines procedures for measuring the accuracy of controls and instruments, ensuring the devices deliver the intended outputs within acceptable tolerances. Additionally, it mandates detailed instructions for use, covering aspects like priming, cleaning, and maintenance to ensure safe and effective operation. Furthermore, the standard emphasizes the importance of risk management throughout the device lifecycle, ensuring potential hazards are identified and mitigated.

The standard emphasizes:

- **International harmonization:** enabling global trade and consistent expectations.
- **Rigorous testing:** specifying procedures to verify compliance, including accuracy of aspiration pressure and diathermy power, limits for hazardous outputs, and sterilization protocols.
- **Operator safety:** highlighting proper training and device use through clear instructions, warnings against inadvertent activation, and reminders to monitor irrigation levels.
- **Visual clarity:** introducing specific symbols for surgical functions to enhance communication.

By establishing the Indian Standard **IS/IEC 80601-2-58 : 2016**, the development and use of safe and effective lens removal and vitrectomy devices is promoted in India, ultimately contributing to patient well-being.