

Regulatory & Compliance Statement

Sceptre Medical India Limited

Sceptre Medical India Limited is committed to maintaining the highest standards of quality, safety, regulatory compliance, and ethical business practices in the manufacture, distribution, and supply of healthcare and medical products.

The Company operates in accordance with applicable regulatory frameworks governing medical devices, healthcare products, and related materials. Our regulatory practices are designed to ensure that all products are manufactured, handled, and distributed in compliance with applicable national and international standards.

Regulatory Compliance

Sceptre Medical India Limited adheres to the regulatory requirements applicable to medical devices and healthcare products in the jurisdictions where its products are manufactured, marketed, or distributed.

In India, medical devices are regulated under the **Medical Devices Rules, 2017**, issued under the **Drugs and Cosmetics Act, 1940** and administered by the **Central Drugs Standard Control Organization (CDSCO)**.

Where applicable, the Company ensures that its products comply with the relevant regulatory classifications, licensing requirements, quality standards, and documentation obligations as prescribed under the applicable regulatory framework.

For products intended for international markets, Sceptre Medical India Limited endeavors to comply with the regulatory and quality requirements applicable in the respective jurisdictions.

Quality Management

Sceptre Medical India Limited is committed to maintaining robust quality management systems designed to ensure consistent product quality and regulatory compliance.

The Company implements structured quality control procedures throughout the product lifecycle, including:

- evaluation and qualification of raw material suppliers
- in-process quality monitoring and testing
- finished product verification and inspection
- documentation and traceability systems
- corrective and preventive action procedures

These processes are designed to ensure that products meet predefined quality and safety standards before they are supplied to customers.

Product safety

Product safety is a fundamental component of the Company's regulatory and quality framework.

Sceptre Medical India Limited evaluates product safety through structured quality control and risk management procedures designed to identify, assess, and mitigate potential risks associated with the manufacture and use of its products.

Product specifications, performance characteristics, and safety parameters are evaluated during development, production, and quality control processes to ensure compliance with applicable standards and intended use requirements.

The Company continually monitors product performance and quality feedback to support ongoing improvements in product safety and reliability.

Information Intended Use of Products

Information relating to products presented on this Website is provided for general informational purposes regarding the Company's product portfolio.

Product descriptions, technical specifications, and other information may be subject to change as part of product development, regulatory updates, or manufacturing improvements.

Users should always refer to the official product labeling, instructions for use, and regulatory documentation accompanying the product for accurate and current information regarding product specifications, intended use, and safety instructions.

Certain products may be intended for professional or institutional use and may require handling or application by trained personnel.

No Medical Advice

Information presented on this Website is not intended to constitute medical advice, clinical guidance, or recommendations regarding diagnosis or treatment.

Healthcare professionals and users should rely on their professional judgment and consult appropriate medical authorities before making decisions relating to patient care or medical treatment.

Regulatory Approvals and Certifications

Certain products offered by Sceptre Medical India Limited may require regulatory approvals, registrations, or certifications before being marketed or used in particular jurisdictions.

The Company endeavors to ensure that all applicable regulatory approvals are obtained prior to commercial distribution where required by law.

However, product availability and regulatory status may differ across countries or regions.

Commitment to Ethical Business Practices

Sceptre Medical India Limited conducts its business operations in accordance with applicable laws, industry standards, and principles of ethical business conduct.

The Company is committed to maintaining transparency, compliance, and responsible practices in its interactions with healthcare institutions, distributors, partners, and regulatory authorities.