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India Proposes **Major Amendments to Medical Devices Rules, 2017**

New Labelling & Testing Fee Requirements Introduced

स्वास्थ्य एवं
परिवार कल्याण मंत्रालय
MINISTRY OF
HEALTH AND FAMILY WELFARE
सत्यमेव जयते

The **Ministry of Health & Family Welfare** has proposed another draft amendment to the Medical Devices Rules, 2017, inviting stakeholder feedback.

Key Highlights

- **New Definition Introduced:** "Certificate of Registration" has been clearly defined, covering registrations issued in Forms MD-2, MD-40, and MD-42.

- **Labelling Requirement for Outsourced Sterilisation:** Manufacturers outsourcing sterilisation must now mention the license number of the sterilisation facility on product labels, enhancing traceability and compliance.

- **Introduction of Ninth Schedule (Fees):** A new fee structure for testing and evaluation of medical devices has been introduced, covering tests like:
  - Implantation, sterility, sutures, syringes, condoms, etc.
  - Additional tests are charged individually
  - Annual 5% increase in testing fees

- **Fee-Linked Compliance**

Testing and evaluation fees are now formally linked to Rule 19 and Rule 69, making fee payment mandatory for related approvals.

- **Minor Definition & Rule Updates**

Certain wording changes and insertions to improve clarity and regulatory structure.

- **Public Consultation Open**

Comments and suggestions can be submitted within **30 days** of publication.

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Stay tuned for the latest updates!

Got questions? We’re just an email away.

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