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The Proposed Medical Devices (Amendment) Rules, 2026: A Comprehensive Analysis of Regulatory Modifications to the Medical Devices Framework

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The Central Government, exercising its rule-making authority under Section 12(1) and Section 33(1) of the Drugs and Cosmetics Act, 1940, has proposed significant amendments to the Medical Devices Rules, 2017, through the publication of draft rules in the Extraordinary Gazette of India on April 10, 2026. The proposed Medical Devices (Amendment) Rules, 2026, notified as G.S.R. 270(E), emerge from the Department of Health and Family Welfare and represent a carefully considered regulatory intervention following consultation with the Drugs Technical Advisory Board. These amendments seek to address existing gaps in the regulatory framework while introducing enhanced transparency measures, particularly concerning testing fee structures and sterilization traceability protocols.

The draft rules have been published in accordance with the standard pre-legislative consultation process mandated under the parent Act, thereby affording stakeholders an opportunity to scrutinize and respond to the proposed modifications. The original Medical Devices Rules, 2017, were promulgated vide notification number 78(E) dated January 31, 2017, and have since served as the foundational regulatory instrument governing the manufacture, import, sale, and distribution of medical devices within the Indian jurisdiction. The present amendments, bearing file reference number X.11035/112/2024-DR, constitute the latest iterative refinement of this regulatory architecture.

The first amendment introduces the short title and commencement provisions for the new rules. The rules shall be designated as the Medical Devices (Amendment) Rules, 2026, and shall come into force on the date of their final publication in the Official Gazette, unless otherwise specified in any particular provision. This standard formulation ensures legal certainty regarding the temporal applicability of the amendments while preserving flexibility for staggered implementation should the Central Government deem such an approach necessary for specific provisions.

The second amendment targets clause (j) of Rule 3, which contains definitions critical to the interpretation and application of the Medical Devices Rules. The proposed modification entails the deletion of the phrase “of a licencee” from the existing clause. This deletion carries substantive implications for the scope of the definition in question, as it removes the limitation that previously tethered the defined term to the context of a licensee. By excising this qualifier, the Central Government appears intent on broadening the applicability of the definition beyond the narrow confines of licensed entities, thereby ensuring comprehensive coverage of all relevant persons or entities falling within the regulatory purview.

The third amendment introduces an entirely new definitional clause, designated as clause (ya), to be inserted immediately after clause (y) of Rule 3. This new clause defines “Certificate of Registration” as a registration certificate granted by either the State Licensing Authority or the Central Licensing Authority, as the case may be, in Form MD-2, Form MD-40, or Form MD-42. The formal codification of this definition addresses a notable lacuna in the existing rules by explicitly recognizing and standardizing the documentation framework for registration certificates. This amendment brings much-needed clarity to the regulatory vocabulary and ensures uniformity in the issuance and recognition of registration documentation across different licensing authorities.

The fourth amendment addresses a matter of considerable practical significance in the medical device manufacturing ecosystem. A new clause (p) is proposed to be inserted after clause (o) of Rule 44, mandating specific labeling requirements for medical device manufacturers who outsource sterilization activities to third-party facilities. Under this provision, where a manufacturer engages another facility possessing a valid license to carry out sterilization processes, the license number of the sterilization site must be conspicuously mentioned on the label of the device itself. The sterilization site license number must be preceded by one of the following designations: “Sterilization sites Manufacturing License Number,” or the abbreviated forms “Ster.Mfg.Lic.No.” or “S.M.L.” This amendment directly responds to growing concerns regarding supply chain transparency and patient safety, ensuring that end-users and regulatory inspectors can readily identify the sterilization source for any given medical device.

The fifth amendment comprises a consequential technical modification to clause (o) of Rule 44. The existing reference to “and (m)” in the said clause is proposed to be substituted with “(m) and (p).” This substitution is necessitated by the insertion of the new clause (p) regarding sterilization site labeling, and it ensures that the cross-referencing within Rule 44 remains internally consistent and legally coherent. While seemingly procedural in nature, such technical corrections are indispensable for maintaining the structural integrity of the statutory text and preventing interpretational ambiguities.

The sixth amendment introduces the most substantively significant innovation of the proposed rules: the insertion of a Ninth Schedule after the existing Eighth Schedule to the Medical Devices Rules, 2017. This Ninth Schedule, titled “Fee for test or evaluation,” establishes a comprehensive and standardized fee structure for eleven distinct categories of medical device testing and evaluation. The schedule is referenced in Rules 19 and 69, thereby integrating the fee framework into the broader regulatory

machinery. The prescribed fees span a diverse range of testing protocols, beginning with implantation tests at five thousand rupees and sterility tests at two thousand rupees. Surgical dressings and syringes and needles each attract a fee of one thousand rupees, while physical or physiochemical tests for perfusion sets and similar devices are priced at two thousand rupees. Surgical sutures command a higher fee of three thousand rupees, reflecting the complexity of their evaluation. Specialized physical and chemical parameter tests, including optical rotation, specific gravity, refractive index, weight per milliliter, and fluorescence, are assessed at two hundred and fifty rupees per individual test. Similarly, absorbency testing, weight per unit area analysis for surgical products, foreign matter examination, extractive value determination, thread count verification, length and width measurement for surgical items, surface active substance analysis, acidity or alkalinity testing, neps evaluation, and setting time assessment are each priced at one hundred and fifty rupees. Condoms and intrauterine devices each attract a testing fee of two thousand five hundred rupees. The bacterial endotoxin test is bifurcated into qualitative and quantitative variants, with the former priced at three thousand rupees and the latter at four thousand five hundred rupees.

The Ninth Schedule further incorporates two critical supplementary provisions. First, for any test or evaluation not explicitly specified in the schedule, the charges shall be determined by the Director or the Medical Device Testing Officer of the relevant laboratory or institute, as the case may be. This residual clause ensures that the fee structure remains adaptable to emerging testing requirements and technological advancements in medical device evaluation. Second, the schedule mandates that the prescribed cost of any test or analysis shall automatically increase by five percent on an annual basis. This built-in escalation mechanism addresses inflationary pressures and ensures that testing facilities remain adequately resourced to maintain quality standards without requiring frequent statutory amendments.

The seventh amendment operationalizes the Ninth Schedule by inserting a new sub-rule (3) after the existing sub-rule (2) of Rule 19. This new provision explicitly states that the fees for test or evaluation shall be those specified in the Ninth Schedule. By creating this statutory linkage, the amendment ensures that all testing activities conducted under Rule 19 are subject to the standardized fee regime, thereby eliminating arbitrary pricing practices and promoting equitable access to regulatory compliance pathways for manufacturers of varying scales.

The eighth and final amendment modifies Rule 69 in Chapter IX of the Medical Devices Rules. The existing provision, which references applications in Form MD-33, is augmented by the insertion of the phrase “accompanied with a fee specified in the Ninth Schedule.” This modification ensures that registration applications submitted under Rule 69 are accompanied by the appropriate testing or evaluation fee as prescribed in the newly inserted Ninth Schedule. The amendment thereby closes any potential loophole that might have permitted fee avoidance in the registration process and reinforces the financial sustainability of the regulatory infrastructure.

The draft rules have been published in the Extraordinary Gazette of India, Part II, Section 3, Sub-section (i), on April 10, 2026, and are now open for public scrutiny and comment. The Central Government has invited objections and suggestions from all persons likely to be affected by the proposed amendments. The consultation window extends for a period of thirty days from the date on which copies of the Gazette containing these draft rules are made available to the public. Following the expiry of this thirty-day period, the draft rules shall be taken into consideration by the Central Government, which retains the discretion to modify, finalize, or withdraw the proposals based on the feedback received. Stakeholders may submit their objections and suggestions in writing to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, located at C Wing, Kartavya Bhavan, New Delhi 110001. Alternatively, electronic submissions may be directed to the official email address drugsdivmohfw@gov.in.

In summation, the proposed Medical Devices (Amendment) Rules, 2026, represent a measured and multifaceted regulatory intervention that addresses critical dimensions of medical device governance in India. The amendments introduce definitional precision, enhance supply chain transparency through sterilization site labelling, and establish a standardized, inflation-adjusted fee structure for medical device testing. By mandating the display of sterilization site license numbers on device labels, the rules significantly advance patient safety and post-market surveillance capabilities. The codification of registration certificate definitions and the integration of testing fees into the application process under Rule 69 further streamline regulatory compliance. Upon finalization, these amendments are poised to strengthen the integrity of India’s medical device regulatory framework, aligning it with international best practices while addressing domestic operational realities. The legal and medical device communities await the culmination of the consultation process with considerable interest, recognizing that the final form of these rules will shape the regulatory landscape for medical device manufacturing, testing, and distribution in India for the foreseeable future.

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