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Legal Metrology (General) Third Amendment Rules, 2025: Regulating Automated Blood Pressure Devices in India

AUTHOR Saswata Banerjee, Aditi Rana

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Introduction

The Ministry of Consumer Affairs, Food and Public Distribution has notified the Legal Metrology (General) Third Amendment Rules, 2025, introducing a pivotal change in the regulatory landscape of medical measuring instruments in India. Notified on July 28, 2025, and effective from July 30, 2025, the amendment brings non-invasive automated sphygmomanometers (digital blood pressure monitors) under the ambit of the Legal Metrology (General) Rules, 2011, aligning India's standards with global practices of accuracy and consumer safety.

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Legal Background

The Legal Metrology Framework in India

Legal Metrology refers to the regulation of measurements and measuring instruments, governed under the Legal Metrology Act, 2009. The Act aims to establish and enforce standards of weights and measures, ensuring fair trade practices and consumer protection. The Legal Metrology (General) Rules, 2011, framed under this Act, provide detailed procedures and technical standards for various instruments.

While previously focused on sectors like retail, manufacturing, packaging, and transportation, the inclusion of medical devices specifically, digital blood pressure monitors, demonstrates an evolving scope to address health-related accuracy and public safety concerns.

Key highlights of the 2025 Amendment

New Insertion: Part VII?B in the Eighth Schedule

The amendment introduces a new section "Part VII?B: Non-Invasive Automated Sphygmomanometers" under the Eighth Schedule of the 2011 Rules. It consists of:

1. Part I – Metrological and Technical Requirements

Outlines the design, safety, and performance standards applicable to arm-type, wrist-type, and thigh-type digital blood pressure measuring instruments. These include:

- Acceptable tolerance limits for pressure accuracy
- Electrical and mechanical safety requirements
- Operating conditions and display specifications

2. Part II – Test Procedures

Specifies the methodologies and equipment for verifying conformity with the above standards, particularly for:

- Cuff pressure indication error thresholds
- Durability and stability testing
- Environmental impact assessments on measurement

Implications for Industry Stakeholders

1. Mandatory Compliance for Manufacturers and Importers

From July 30, 2025, all automated blood pressure measuring devices whether manufactured in India or imported must conform to the new metrological and technical standards. Non-compliance may lead to:

- Rejection of import consignments
- Seizure of non-compliant stock
- Penalties under the Legal Metrology Act, 2009

2. Inspection and Certification

Legal Metrology Officers (LMOs) will now assess these devices under the newly specified testing and certification protocols. Manufacturers and importers are expected to:

- Maintain compliance records
- Affix proper declarations and labels
- Undergo verification and stamping processes where applicable

3. Impact on Hospitals, Clinics, and Retailers

Healthcare institutions and sellers must ensure procurement from compliant manufacturers and authorized importers, or risk inadvertently distributing non-conforming devices.

Alignment with Global and Domestic Trends

This amendment aligns with a growing international consensus on standardizing diagnostic medical equipment. Comparable standards exist under:

- ISO 81060-2:2018 – Non-invasive sphygmomanometers Clinical investigation
- WHO's medical device regulations
- Domestic alignment with India's Medical Devices Rules, 2017 and Drugs and Cosmetics Act, 1940, especially for Class A/B diagnostic devices

Conclusion

The Legal Metrology (General) Third Amendment Rules, 2025 is a strategic regulatory intervention that reflects India's intent to bring medical diagnostic accuracy under the purview of consumer protection and public health safety. For manufacturers, importers, and healthcare providers, the onus is now on ensuring robust technical compliance, labeling transparency, and documentation, backed by timely certification and testing.

As medical technology continues to permeate public and private health domains, regulatory vigilance through Legal Metrology is set to play a critical role in building trust, preventing harm, and ensuring fair trade.

For more details, write to us at: contact@indialaw.in

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