**MINISTRY OF HEALTH AND FAMILY WELFARE**

**(Department of Health and Family Welfare)**

**NOTIFICATION**

New Delhi, the 10th October, 2025

**G.S.R. 748(E).—** The following draft of certain rules to amend Medical Device Rules, 2017, which the Central Government proposes to make, in exercise of the powers conferred by Sub-section (1) of section 12 and Sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), is hereby published after consultation with the Drugs Technical Advisory Board for information of all persons likely to be affected thereby and notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of thirty days from the date on which copies of the Gazette of India containing these draft rules are made available to public;

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government;

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 545, A Wing, Nirman Bhavan, New Delhi - 110011 or emailed at drugsdiv-mohfw@gov.in.

**DRAFT RULES**

1. (i) These rules may be called the Medical Devices (Amendment) Rules, 2024.

   (ii) These rules shall, unless specified otherwise, come into force on the date of their final publication in the Official Gazette.

2. In the Medical Devices Rules 2017, after Rule 18, the following rule shall be inserted, namely: -

18A. Qualifications of Inspector (Medical Device). - A person who is appointed as an Inspector under the Act shall be a person who has a degree in-

i. Bachelors of engineering technology in Bio Medical or Chemical or Mechanical or Electrical or Electronics or Instrumentation or Bio-Technology or Polymer or Computer Science or Medical Electronics Engineering from a recognised university or institute; Or

ii. Bachelors degree in Pharmacy or Pharmaceutical Science or Microbiology or Bio- Chemistry or Chemistry or Life Sciences from a recognised university or institute.

18B. Qualifications of Government analyst.- A person who is appointed as a Government analyst under the Act shall be a person who has a degree in-

i. Bachelors of engineering technology in Bio Medical or Chemical or Mechanical or Electrical or Electronics or Instrumentation or Bio-Technology or Polymer or Computer Science or Medical Electronics Engineering from a recognised university or institute; Or

ii. Bachelors degree in Pharmacy or Pharmaceutical Science or Microbiology or Bio- Chemistry or Chemistry or Life Sciences from a recognised university or institute.

[F. No. X.11012/04/2025 -DR]
NIKHIL GAJRAJ, Jt. Secy.

**Note:** The principal rules were published in the Official Gazette vide notification number G.S.R.78(E), dated 31st January,2017 and last amended vide notification number GSR 409 (E) dated 2nd June, 2023.

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