

# GOVERNMENT NOTIFIES MEDICAL DEVICES AS DRUGS, INDUSTRY CAUTIOUS

Relevant for: Developmental Issues | Topic: Health & Sanitation and related issues

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The Union Health Ministry has notified medical equipment used on humans as drugs under Section 3 of the Drugs and Cosmetics Act with effect from April 1, 2020. The Ministry, through a gazette notification, also released the Medical Devices Amendment Rules, 2020, for mandatory registration of medical devices.

Aimed at ensuring that all medical devices meet certain standards of quality and efficacy, the notification will also make medical device companies accountable for quality and safety of their products, noted a senior health official.

Stating that most small manufacturers cannot comply with the rules, Rajiv Nath, Coordinator of Association of Indian Medical Device Industry (AIMED), said all low-risk equipment made by small manufacturers would find it tough to comply with and to have qualified regulatory staff to meet the Medical Device and Diagnostic Rules (MDR) Schedule 5. "The Health Ministry has been unwilling to amend this, though NITI Aayog is supportive and has assured to make a provision in its draft Bill," said Mr. Nath.

Welcoming the move, the Medical Technology Association of India (MTAI), association of global and Indian medical devices, said this move was a continuation of the Medical Devices Rules 2017.

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