

Medical equipment used on humans or animals notified as 'drugs'

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Source: PRS India & Economic Times

In order to ensure that all medical devices meet certain standards of quality, the Ministry of Health and Family Welfare notified **all medical equipment intended for use on human beings or animals as 'drugs' under the Drugs and Cosmetics Act, 1940**. This will come effect from April 1, 2020.

Impact

All imported, as well as locally manufactured medical devices sold in India, will be required to clear specific safety and quality standards before they are introduced in the Indian market.

Medical equipment

Medical equipment includes all implantable medical devices, CT scan, MRI equipment, defibrillators, dialysis machine, PET equipment, X-ray machine and bone marrow cell separator.

Key highlights

- According to the notification, all devices including all instruments, apparatus, appliances and implants, used alone or in combination for several purposes will be covered.
- These purposes include
 1. Diagnosis, prevention, monitoring, or treatment of any disease
 2. Investigation, replacement, or modification of the anatomy, and

3. Supporting or sustaining life will.

- Further, the Union Ministry notified the **Medical Devices (Amendment) Rules 2020** which provide for **mandatory registration of medical devices**.
- The notification also provides timelines by when all medical devices of varying risks should be registered.