

**File No. MED-12012(18)/1/2026-eoffice
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Medical Devices Division)**

Food & Drugs Administration Bhawan,
Kotla road, New Delhi-110002

Dated:

27 MAR 2026

Circular

Subject: Import, manufacturing, sale etc. of medical devices intended for In-Vitro Fertilization viz., IUI (Intrauterine Insemination) kits, centrifuge for sperm washing etc. used for Assisted Reproductive Technology related procedures – reg.

As you are aware that, all the medical devices are regulated under the provisions of Drugs and Cosmetics Act,1940 and Medical Devices Rules,2017 thereunder and license is required for its import, manufacturing, sale and distribution in the country except Class A non-sterile and non-measuring medical device. The devices used for In Vitro Fertilization viz., IUI (Intrauterine Insemination) kits, Centrifuge for sperm washing etc. used for Assisted Reproductive Technology related procedures covers under the definition of medical device.

It has been brought to the notice of this office that firms are selling medical devices intended for In Vitro Fertilization viz., IUI (Intrauterine Insemination) kits, Centrifuge for sperm washing etc. used for Assisted Reproductive Technology related procedures without obtaining license from licensing authority under Medical Devices Rules, 2017.

In light of the above, you are requested to keep strict vigil & ensure that no such devices used for In Vitro Fertilization for Assisted Reproductive Technology related procedures are being imported, manufactured, distributed, sold without abidance to the Drugs and Cosmetics Act,1940 and Medical Devices Rules, 2017.

Yours faithfully,


(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

To,

1. All States / UTs Drugs Control & Licensing Authorities
2. All Zonal / Sub-Zonal/Port Offices of CDSCO

3. All stakeholders through CDSCO Website

Copy for information to:

1. US, Drugs Regulation Section, MoHFW, New Delhi.