

File No. MED/71/2026-eoffice
Government of India
Ministry of Health and Family Welfare
Directorate General of Health Services
Central Drugs Standard Control Organization
(Medical Devices Division)

FDA Bhawan, Kotla Road,
New Delhi – 110002

Dated:

23 JUN 2026

CIRCULAR

Subject: Sale of In-Vitro Fertilization media, reagents and related consumables used in Assisted Reproductive Technology procedures - reg.

All the medical devices are regulated under the provisions of Medical Devices Rules, 2017 for ensuring the quality, safety and performance of the devices. The media, reagents etc. intended for use in Assisted Reproductive Technology such as In-Vitro Fertilization, Cryopreservation etc. are also covered under the purview of the said rules and a license is required to import or manufacture such products under Medical Devices Rules, 2017.

Currently, these products are being used by assisted reproductive technology clinics and banks registered under the Assisted Reproductive Technology (Regulation) Act, 2021 and the Surrogacy (Regulation) Act, 2021 for the regulation of safe and ethical practice of assisted reproductive technology services for addressing the issues of reproductive health, and for the regulation of practice and process of surrogacy. The use of such products by facilities other than registered centres may pose risk of misuse of the assisted reproductive technology services.

It has been brought to notice of this office that Assisted Reproductive Technology Media etc. are being supplied to facilities other than those that are registered under the said Acts thereby posing risk to patient health and welfare.

In light of the above, it is hereby informed that all the stakeholders are requested to ensure that the supply of such products shall be carried out to the centres that are registered under the Assisted Reproductive Technology (Regulation) Act, 2021 and the Surrogacy (Regulation) Act, 2021 to safeguard ethical reproductive healthcare practices in India.

This circular is issued for information in public interest.


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

To:

All the stakeholders

Copy to: (1) All State/UTs Licensing Authorities
(2) All Zonal/Sub-zonal offices of CDSCO
(3) CDSCO website