File no. MED-13/87/2025-eoffice
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Medical Device Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002,
Dated 17 NOV 2025

Circular

Subject: Requirement of License issued by CDSCO/State Licensing Authorities in procurement of Medical Devices by procurement agencies-regarding

It has been brought to the notice of this office that the various procurement agencies including Hospitals are insisting for requirement of USFDA/CE certification as one of the requirements of technical bid for procurement of Medical Devices in the country.

Kind attention is invited that, the Ministry of Health and Family Welfare has come up with Medical Devices Rule,2017 under the Drugs and Cosmetics Act,1940 for regulation of Medical Devices in the country to ensure its quality, safety and performance. Currently, all the Medical Devices are regulated under said Rule and license is a mandatory requirement for its import, manufacturing, sale and distribution in the country. No Medical Devices can be sold in India without valid license obtained from Licensing Authorities. Based on the risk, Medical devices are classified into four categories viz. low risk Class A, low to moderate risk Class B, Moderate to high risk Class C and high risk Class D.

The manufacturing license for risk Class A & risk Class B medical devices and sale license for all risk class of Medical devices are issued by the concerned State/UT Licensing Authorities (SLAs). The Import license for all risk class of Medical devices and manufacturing license for risk Class C & risk Class D are issued by the Central Licensing Authority i.e. Central Drugs Standard Control Organization(CDSCO) based on the detailed technical review & conformance of Quality Management System in manufacturing of Medical Devices. The applicant shall obtain relevant license from the Concerned Licensing Authorities for sale and distribution of Medical Devices in the country.

In light of the above, all the procurement agencies including Hospitals, Health Institutions, etc., are requested that the CDSCO license or the license issued by the State/UTs Licensing Authority under the Medical Devices Rules, 2017, shall be made mandatory as a part of the requirements for procurement of Medical Devices, without which the medical device cannot be sold in the country. Any other certifications which is required by the procurement agency should be over and above of CDSCO or SLA Licensing Authority approval, under the said rules.

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

To,

All Heads of the Institute/Organizations/Hospitals etc.

Copy for information to:

1. PPS to Secretary Health
2. PS to DGHS
3. PS to JS (R)