File No.:MED/2/2024-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: 03 APR 2024

To,
All stakeholders through CDSCO website.

Subject: Strengthening of private Medical Devices Testing Laboratory in the country - Reg.

You may be aware that CDSCO is the National Regulatory Authority under Ministry of Health and Family Welfare responsible for ensuring the quality, safety and performance of medical devices under Medical Device Rules, 2017.

In consequent to implementation of S.O. 648(E) dated 11.02.2020 and G.S.R. No. 102 (E) dated 11.02.2020, all the medical devices have come under Drugs and Cosmetics Act, 1940 and Medical Device Rules, 2017.

Presently, certain private testing labs have been registered under MDR, 2017 for testing & examination of certain medical devices in the country on behalf of the manufacturer. In order to strengthen the private testing facility for medical devices in the country, this office is in the process of identifying the existing private labs having the facility to test the medical devices, so that these labs may be registered under MDR, 2017. It is observed that your organization is having testing facility for carrying out various tests of medical devices. The medical devices require various tests including Physical, chemical, microbiology, mechanical & electrical etc.,

In view of above, it is requested that you may kindly identify your facility for testing of the above tests for medical devices and submit the application in Form MD-39 along with the requisite information with fees as per MDR, 2017 for registration of testing laboratory behalf of the manufacturer.

This is for your information and necessary action in the matter.

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