File No.: MED/48/2024-eoffice
Central Drugs Standard Control Organisation
Government of India
Ministry of Health and Family Welfare

FDA Bhawan, New Delhi
Dated 29 MAY 2024

CIRCULAR

Subject: Testing and evaluation of Medical Devices(MD)/ In vitro diagnostics(IVDs) by Medical Devices Testing Laboratories in the country - Reg.

In order to ensure the quality, safety and performance of Medical Devices(MD)/ In vitro diagnostics (IVDs), the Ministry of Health and Family Welfare, Government of India has granted registration of Laboratory for carrying out Test or Evaluation of a Medical Device on behalf of a manufacturer, under Chapter X of Medical Device Rules 2017 to strengthen the testing facility in the country

It is pertinent to mention that consequent to the implementation of MDR 2017 with effect from 01/01/2018, the Drug Rules 1945 are no longer applicable for MDs/IVDs. Also, the product standards of Medical Devices as prescribed under Rule 7 of the Medical Device Rules (MDR) are mandatory as under.

"(1) The medical device shall conform to the standards laid down by the Bureau of Indian Standards established under section 3 of the Bureau of Indian Standards Act, 1985 or as may be notified by the Ministry of Health and Family Welfare in the Central Government, from time to time.
(2) Where no relevant Standard of any medical device has been laid down under sub-rule (1), such device shall conform to the standard laid down by the International Organisation for Standardisation (ISO) or the International Electro Technical Commission (IEC), or by any other pharmacopoeial standards.
(3) In case of the standards which have not been specified under sub-rule (1) and sub-rule (2), the device shall conform to the validated manufacturer's standards."

It has been observed that the Medical Devices which has BIS standards available, the testing of such devices are not being carried out as per BIS standards.

In view of the above, it may be ensured that the samples of the medical devices shall comply to the BIS standards for its quality and performance and accordingly the medical devices shall be tested with respect to the requirements as prescribed in the BIS standards. If no BIS standard is available, then only other standards as mentioned in Rule 7 of the MDR may be applied.

This is for strict compliance.

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

To
All Medical Devices Testing Laboratories registered with CDSCO
Copy to:
All Stakeholders through website.
All Medical Device and In vitro diagnostics Associations in India