F. No. MED-15/35/2024-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: 15 MAY 2024

CIRCULAR

Subject: Retention of license or certificates under Medical Devices Rules, 2017- reg.

You may be aware that the license for manufacturing or import of Medical Devices and Registration Certificate for QMS Audit by Notified Body as well as for Medical Devices Testing Laboratory is issued in perpetuity, provided a payment of requisite fee may be deposited in stipulated timeline under MDR, 2017 or unless it is suspended or cancelled by the Licensing Authority.

Further, the endorsements to the licenses/certificates issued will also be valid till the validity of its base license/certificate. If the requisite fee is not deposited by the applicant as per stipulated timeline, the license/certificate shall be deemed to have been cancelled.

In view of the above, all the stakeholders are requested to ensure that the requisite fee may be deposited in appropriate account of the Government, well before the stipulated timeline under MDR, 2017 and also submit the application to the Licensing Authority in order to maintain continuity of the product in the market.

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

To,

1. All stakeholders through CDSCO Website
2. All the Association of Medical Devices through email
3. All the Notified bodies through email
4. All the Medical Device Testing laboratory through email