396/C

29/Misc/03/2022-DC (94)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation

Dated: 25/4/2022

OFFICE MEMMORANDUM

Subject: Licensing regime of Class A & Class B medical devices which are under compulsory registration as per GSR 102(E) dated 11.02.2020 under Medical Devices Rules-2017 w.e.f 01.10.2022-regarding.

As you are aware that the class-A & class-B non notified medical devices which are currently under mandatory registration will be under licensing regime with effect from 01.10.2022 as per GSR 102(E) dated 11.02.2020.

As per Medical Devices Rules-2017, for class A medical devices the audit to verify the QMS may be carried out within 120 days from the date of issuance of license and for class B devices audit need to be carried out by Notified body prior to the issuance of the license by concerned State Licensing Authority.

In order to have smooth transition from mandatory registration to licensing regime, it is requested that processing for issuance of license to the applicants for class A & class B shall be initiated proactively so that the licensure can be issued in the stipulated time i.e. from 01.10.2022 under Medical Devices Rules-2017.

(Dr.V.G.Somani)
Drugs Controller General (I)

To,

1. All State/UT Drug Licensing Authorities
2. Zonal/sub-zonal offices of CDSCO