Government of India
Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
(Medical Devices and Diagnostics Division)
FDA Bhawan, Kotla Road, New Delhi-110002

File No: IVD/Misc/045/DCGI/18

Dated, 09 APR 2018

To:

All Zonal and Sub Zonal Offices of CDSCO

Subject: Inspection of manufacturing site of Class C and Class D medical devices including In-Vitro Diagnostic Medical Devices under the provisions of MDR 2017 - Regarding

Sir,

It has been decided that, application made to the Central Licensing Authority through the online portal i.e cdscomdonline.gov.in for licence or loan licence to manufacture for sale or for distribution, as the case may be, of Class C or Class D medical device including In-Vitro Diagnostic Medical Devices in Form MD-7 or Form MD-8, respectively shall be scrutinized and processed by the concern CDSCO Zonal or Sub Zonal Offices within a period of forty five days from the date of online submission of application. In case, where the documents are found to be complete and in order, the respective CDSCO office shall cause an inspection of the manufacturing site as earlier as possible as per rules. In case of critical cases MDO or ADC(I) from CDSCO (HQ) may be included in the inspection team.

Yours Faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (India)