File No. IVD/Misc/023/DCGI/18
Directorate General of Health Services
Central Drug Standard Control Organisation
Office of Drugs Controller General (India)

FDA Bhawan, Kotla Road,
New Delhi
Date: 15.02.2018.

To,

All Medical Device & In-Vitro Diagnostics Manufacturers,

Subject: One day Workshop programme for all Medical Device & In-Vitro Diagnostics manufacturers on new online Medical Device Portal under Medical Devices Rules 2017 – regarding.

Sir,

Central Drugs Standard Control Organization (CDSCO) is regulating quality, safety and efficacy of the drugs, cosmetics and medical devices in the country under the provision of the Drugs and Cosmetics Act, 1940 and the Rules framed thereunder. Recently, the Health Ministry & Family Welfare has notified new medical Device Rules 2017 vide GSR 78(E) dated 31.01.2017 which is now effective from 01.01.2018.

As per the current Medical Device Rule 2017 (MDR-2017, One of the mandate of MDR-2017 that all application for grant of manufacturing license shall be process through online mode. Accordingly, CDAC has prepared new online Sugam portal for medical device for all stakeholders.

In this regard, CDAC is organizing one day workshop programme for Medical Devices & IVDs manufactures on new online Medical Device Portal under Medical Device Rules-2017 on 19.02.2018 at 11:00 hrs to 15:30 hrs at Centre for Development of Advanced Computing, B 30, Block B, Industrial Area, Sector 62, Noida, Uttar Pradesh 201309.

The main objective of this workshop programme to provide brief description of Medical Device Portal, which includes registration of new Medical Device portal, login and update of user profile and submission of various forms as per MDR-2017(Agenda is attached as Annexure-I)

You are therefore requested to nominate one authorized representative from each manufacturer to participate in workshop. The details of nominated participant may be forwarded to this office latest by 16.02.2018 through email id: ithelpdeskcdscomd@gmail.com, ddcimd-cdsco@nic.in . Registration will be accepted on First come-First serve basis. It is also stated that the all expenditure incurred by the participants will be borne by their own.

Note: Participants are requested to mention their confirmation through mail as **"Registration for Workshop dated on 19.02.2018"** in subject.

Yours Faithfully,

(Aseem Sahu)
Deputy Drugs Controller (I)

Copy to:

1. The Director CDAC, B 30, Block B, Industrial Area, Sector 62, Noida, Uttar Pradesh 201309.
2. The Director Admin, CDSCO (HQ), FDA Bhawan, Kotla Road, New Delhi.
3. DCGI Secretariat
4. Web portal of CDSCO

ANNEXURE-I

Agenda: Workshop for Manufacturers
19th Feb 2018, 11:00 AM

Venue	CDAC, B-30 Sector 62, Noida 201307
Date & Time	19th Feb 2018, 11:00 AM to 03:30 PM
Facilitator	CDAC, Noida
Invited Participants	Manufacturers of Medical Devices, Officials from CDSCO

Agenda Items	
1	Brief description of Medical Device Portal
2	How to Register in the New Medical Device Portal
3	How to login and update User Profile
4	How to submit various forms (MD-3, MD-4, MD-7 & MD-8)
5	How to upload checklist documents
6	How to check Status of Application

Instructions
1. Only one representative/participant is allowed from one organization.
2. Participants should bring their laptop with them
3. Participants should have a fair understanding about Medical Device rules released in Gazette (2017)
4. Participants are requested to adhere to the workshop timings