

File No: 29/ Misc.3/2017-DC (26)
Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

Date:07.04.2017

Notice

**Subject: Meeting for the registration of notified body through online portal
- Regarding**

As you are aware that Medical Device Rules 2017 have already been published vide G.S.R. 78 (E) dated 31.01.2017 under Drugs and Cosmetic Act, 1940 to regulate the Clinical Investigation, manufacture, import, sale and distribution of the medical devices. The Chapter III (Rule 13) of Medical Device Rule 2017 provides for the registration of notified bodies with CDSCO.

Subsequently, with effect from the 1st day of the July, 2017, the Notified Body may file their application to the Central Licensing Authority for registration in Form MD-1 through online portal to carry out the audit of manufacturing sites of Class A & Class B medical devices to verify conformance with the Quality Management System and other applicable standards.

In this regard, CDSCO has put in place an online portal for the registration of notified bodies.

Further, it has been decided to convene a meeting of all notified bodies on 17.04.2017 at 11:00 AM at FDA Bhawan, Kotla Road, New Delhi to demonstrate the alpha version and validation of online submission of application for their registration.

You are requested to kindly make it convenient to attend the said meeting. The nomination may please be forwarded along with line of confirmation to this mail ID- ddcimd-cdsco@nic.in.

(Dr.S. Eswara Reddy)
Joint Drugs Controller (I)

To,

1. All notified Bodies
2. JDC(I)/DDC(I)/ADC(I) of Medical Device Division, CDSCO(HQ)

Copy to

1. PPS to JS (KLS)
2. PS to DCG(I)
3. Director (Administration), CDSCO(HQ)