

Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
Medical Device and Diagnostic Division

Food and Drug Administration Bhawan
Kotla Road, New Delhi-110002

Dated **27 DEC 2012**

File No.: 29/Misc./05/2010-DC

To,
All the State Drugs Controller

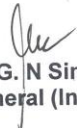
SUB: -Guidance Documents on common submission format for Manufacture of Medical Devices (Form-28) under CLAA scheme -Reg.

Sir,

In India Import, Manufacture, Sale and distribution of Medical Devices is regulated under Drugs and Cosmetics Act 1940 and Rules 1945. The CDSCO had issued guidelines for manufacture and import of Medical Devices with the approval of Ministry of Health and Family Welfare which was effective from 01-03-2006. To address some of the issues of these guidelines the guidance documents have been prepared to specify the general requirements on common submission format for Manufacture of Medical Devices (Form-28) under CLAA scheme. This guidance will help the industry to submit the required documents in a more realistic manner, which in turn will also help drugs regulators to review such application in systematic way. It is apparent that this structured application with comprehensive and rational contents will help the regulators to review and take necessary actions in a better way and would also ease the preparation of electronic submissions.

The Guidance Documents had been uploaded on the CDSCO website on 31-10-2012 (http://cdsco.nic.in/Medical_div/guidance.htm).

Yours faithfully,


(Dr. G. N Singh)
Drugs Controller General (India)