

**Central Drugs Standard Control Organisation  
Directorate General of Health Services  
Ministry of Health and Family Welfare**

Food and Drugs Administration Bhavan  
Kotla Road, New Delhi – 110002

Date: 1 SEP 2010

File No: 29/Misc/5/2010-DC

**Office Order**

This is with reference to the following Draft Guidance Documents uploaded on CDSCO website for regulation of Medical Devices in India:

1. Guidance Document on Common Submission Format for Registration of Medical Devices in India
2. Guidance document on application for grant of Licence in Form-28 for manufacture of Medical Devices in India under CLAA Scheme
3. Guidance Document on Common Submission Format for Import Licence in Form 10 of Medical Devices in India
4. Requirements for Conducting Clinical Trial(s) of Medical Devices in India

Initially a time period of 20 days was given by this office for submitting Suggestions/comments on the above mentioned Draft Guidance Documents. However, based on the requests received by this office from the Industry and Medical Device Associations, last date for submission of suggestions/comments on Draft Guidance documents is extended upto 30.09.2010.



**Dr. S Eswara Reddy  
Asstt. Drugs Controller (I)**