
# CDSCO LICENSE & SALE

DIVYA GANAPATHY

# CONTENTS

**ISO13485:2012, *Medical devices – Quality management systems – Requirements for regulatory purposes***

***Focus on the following items:***

- Section 4.0 - Quality Management System Requirements Section 5.0 - Management Responsibility
- Section 6.0 - Resource Management
- Section 7.0 - Product Realization
- Section 8.0 - Measurement, Analysis, and Improvement

# CDSCO

- CDSCO (Central Drugs Standard Control Organization) is Indian is regulation for the medical device industry under the regulatory provisions of the Drugs & Cosmetics Act 1940 & Rules 1945.
- The Central Drugs Standard Control Organization i.e CDSCO is the national regulatory body for Indian medical devices and pharmaceuticals. It's a licensing authority.
- The Central Drugs Standard Control Organization (CDSCO) medical device is the national regulatory body for India.

The headquarter of the Central Drugs Standard Control Organization(CDSCO) is located in New Delhi.

# CDSCO ROLE

- Approval of new drugs and clinical trials.
- Import CDSCO registration & licensing.
- Licensing of blood banks, vaccines and some medical devices.
- Amendment to Drugs & Cosmetics Act and rules.
- Participation in WHO GMP certification schemes.
- Grant to test license, personal license,
- NOC’s for export.
- Testing of drugs by central labs

# MEDICAL DEVICE REGISTRATION IN INDIA

Step 1: Is your product a Medical Device?

Step 2: Does it fall under the category of Notified Devices?

Step 3: you should firstly appoint an India Authorized Agent to interact with the Central Drugs Standard Control Organization (CDSCO) on your behalf.

Your Agent must have a valid wholesale license (Forms 20B and 21B).

Step 4: Medical device or IVD on the list above, file application for Device Registration Certificate to CDSCO using Form 40. Schedules D-1 and D-2 must be included, as well as verification of compliance with US, Canadian, European, Japanese or Australian medical device regulations

Step 5: Medical Device manufacturers require a Form 45 (New Drug License) in support of the Form 40 application.

# MEDICAL DEVICE REGISTRATION IN INDIA

Step 6: obtain Registration Certificate Form 41 from CDSCO. The certificate is valid for up to 3 years.

Step 7:  Identify your distributor in India (holding forms 20B and 21B).

**Step 8:** Apply for Import License using Forms 8 and 9 available from CDSCO. You must identify your chosen distributors on these forms.

**Step 9:** Obtain Import License (Form 10) from CDSCO and CDSCO License is valid for up to 3 years.

**Step 10:** You are now authorized to market your device in India.

# Contact us for more information:

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