

**GUIDANCE DOCUMENT FOR OBTAINING MARKET STANDING OR NON-CONVICTION  
CERTIFICATE OF NOTIFIED MEDICAL DEVICES**

**Guidance Document  
(Medical Device and Diagnostics Division)**

**Title: GUIDANCE DOCUMENT FOR  
OBTAINING MARKET STANDING/NON-  
CONVICTION CERTIFICATE OF NOTIFIED  
MEDICAL DEVICES**

**Doc No.: CDSCO/MD/GD/MSC/NC/01/00**

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**CENTRAL DRUGS STANDARD CONTROL ORGANIZATION  
DIRECTORATE GENERAL OF HEALTH SERVICES  
MINISTRY OF HEALTH & FAMILY WELFARE  
GOVERNMENT OF INDIA**

## GUIDANCE DOCUMENT FOR OBTAINING MARKET STANDING OR NON-CONVICTION CERTIFICATE OF NOTIFIED MEDICAL DEVICES

- 1. PURPOSE:** To provide guidance to Indian manufacturers or importers for submission of application to CDSCO for obtaining Market Standing or Non-Conviction Certificate of Notified Medical Devices.
- 2. SCOPE:** This guidance document is applicable to those medical device manufacturers or importers in India who are having valid manufacturing license or import license and intend to obtain Market Standing or Non-Conviction Certificate of Class C & D Notified Medical for tender purpose.
- 3. MODE OF SUBMISSION:** Offline (Hard Copy)
- 4. GUIDANCE:**

An application shall be made to the Central Licensing Authority by the manufacturer, having a valid License to manufacture for sale or for distribution of notified Medical Device

**4.1 Covering Letter** – The covering letter should clearly specify the intent of the application. The list of documents that are being submitted (Index with page no's) as well as any other important and relevant information may be provided in the covering letter. The covering letter should be duly signed and stamped by the authorized signatory, indicating the name & designation of the authorized signatory along with the name and address of the firm.

**4.2** A valid copy of **license to manufacture** for Sale or for Distribution or **Import License** of Medical Devices along with approved product list issued by Central licensing Authority.

**4.3 Bills of Entry and Import Details** (in case of import) of last 3 years for applied products.

**4.4 Legal Undertaking** on 100 Rupees registered notarized stamp from the manufacturer or importer stating that no action has been initiated against them or been convicted due to adverse events, market complaint and Not of Standard Quality (NSQ) report of any product in India.

**4.5 List of products** for which the Market Standing or Non-Conviction Certificate is required (in compact Disc also).

**Note:** Validity of the Market Standing or Non-Conviction Certificate will be 1 year from the date of issuance or till validity of license, whichever is earlier.