

Central Drugs Standard Control Organization

(Medical Devices Division)

Guidance Document

Title: Guidance document on Market Standing Certificate (MSC) and Non-Conviction Certificate (NCC) for Licensed Medical Devices

Doc No.: CDSCO/MD/GD/MSD/NCC/01/2024

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

GUIDANCE DOCUMENT ON MARKET STANDING CERTIFICATE (MSC) AND NON-CONVICTION CERTIFICATE (NCC)

- 1. PURPOSE:** To provide guidance to Indian manufacturers or importers for submission of application to the Licensing Authority for obtaining Market Standing Certificate or/and Non Conviction Certificate for licensed Medical Devices for tender purposes, etc.
- 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 under the Medical Devices Rules, 2017 and intend to obtain Market Standing and/or Non-Conviction Certificate for licensed medical devices for tender purposes, etc.
- 3. MODE OF SUBMISSION:** Online (www.cdscmdonline.gov.in)

4. GUIDANCE:

An application shall be made to the Central Licensing Authority (CLA) for Class C and Class D medical devices licensed under a valid manufacturing license or for devices of all classes licensed under a valid import license for sale or distribution of medical devices under the Medical Devices Rules, 2017.

In case of Class A and Class B medical devices licensed under a valid manufacturing license for sale or for distribution of medical devices under the Medical Devices Rules, 2017, the applications shall be made to the State Licensing Authority (SLA).

4.1 Covering Letter: The covering letter should clearly specify the intent of the application. The list of documents that are being submitted 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 Application Form: The system-generated application form should reflect the license number and the product list for which MSC or/and NCC is requested.

4.3 Import/Manufacturing License: A valid copy of license to manufacture/import for Sale or for Distribution issued by the concerned Licensing Authority.

4.4 Market Standing Details (only for MSC): As an evidence for the market standing of devices in the Indian market, the applicant shall submit the following:

i) In case of Import: Sales details duly certified by CA or Bills of Entry

ii) In case of manufacturing: Sales details duly certified by CA

The above-mentioned details shall be submitted for the duration of last 3 years from the date of submission of the MSC application or from the date of grant of license, whichever is later, for all applied products.

4.5 Legal Undertaking shall be submitted on a 100 Rupees registered notarized stamp (recently notarized) by 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 as prescribed in **Annexure A**.

Note:

1. The validity of the MSC will be 1 year from the date of issuance or till validity of license, whichever is earlier, provided no regulatory action has been initiated by the Licensing Authority on the applied products.
2. In case of MSC, the applicant may ensure that all applied brands and model numbers are mentioned in the submitted market standing details (as mentioned in **Section 4.3** of this document).
3. Please refer **Annexure B** for the checklist of documents to be submitted with the application.

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ANNEXURE A

**FORMAT FOR LEGAL UNDERTAKING TO BE SUBMITTED ON A Rs. 100
STAMP PAPER AND DULY NOTARIZED**

We, M/s. _____ (**Firm name**), registered at _____
(**Registered address**), do hereby declare that:

1. We are applying for Market Standing Certificate (MSC) and/or Non Conviction Certificate (NCC) for the products, as mentioned below, licensed under the valid manufacturing/import license number _____ (**manufacturing/import license number**) dated _____ (**date of issue of license**) for sale or for distribution of medical devices in India under the Medical Devices Rules, 2017.

List of applied products for MSC/NCC:

S. No.	Generic Name	Brand Name	Model No.

(In case, the number of products is more, a separate product list may be attached that is duly notarized)

2. As on date _____ (**date of undertaking**), no action has been initiated against us or been convicted due to adverse events, market complaints, and Not of Standard Quality (NSQ) reports of the products as mentioned in this undertaking and licensed under the above-stated manufacturing/import license under the provisions of the Drugs and Cosmetics Act, 1940 and the Medical Devices Rules, 2017 thereunder.

**Sign and Stamp
(Authorized signatory)**

Notary Stamp with Date

ANNEXURE B**CHECKLIST FOR NON CONVICTION CERTIFICATE (NCC) APPLICATION**

S. No.	Checklist
1.	Cover letter
2.	Application for NCC
3.	A copy of valid Manufacturing/import license (along with retention application file number for all applied products, if applicable)
4.	Legal Undertaking on 100 Rupees registered notarized stamp (recently notarized) 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 applied product

CHECKLIST FOR MARKET STANDING CERTIFICATE (MSC) APPLICATION

S. No.	Checklist
1.	Cover letter
2.	Application for MSC
3.	A copy of valid Manufacturing/import license (along with retention application file number for all applied products, if applicable)
4.	Copy of original Bills of Entry or Sales details duly certified by CA for the duration of last 3 years from the date of submission of the MSC application or from the date of grant of license, whichever is later, for all applied products (in case of import)
5.	Copy of Sales details duly certified by CA for the duration of last 3 years from the date of submission of the MSC application or from the date of grant of license, whichever is later, for all applied products (in case of manufacturing)
6.	Legal Undertaking on 100 Rupees registered notarized stamp (recently notarized) 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 applied product