Central Drugs Standard Control Organization

(Medical Devices Division)

Guidance Document

Title: Guidance Document for obtaining Free Sale Certificate (FSC) for licensed medical devices in India

Doc No.: CDSCO/MD/GD/FSC/02/2024

GUIDANCE DOCUMENT ON FREE SALE CERTIFICATE (FSC)

1. **PURPOSE:** To provide guidance to Indian manufacturers for submission of application to the Licensing Authority for obtaining Free Sale Certificate (FSC) for export purposes.

2. **SCOPE:** This guidance document is applicable to those medical device manufacturers in India who are having valid manufacturing license and intend to obtain Free Sale Certificate for export of medical devices.

3. **MODE OF SUBMISSION:** Online (www.cdscomdonline.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 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 FSC is requested.

4.3 Bharatkosh Challan Receipt: The requisite fees prescribed in the Second Schedule of the Medical Devices Rules, 2017 for FSC shall be paid through the online Bharatkosh challan by the applicant, at the rate of 1000 INR per category of medical device(s).

4.4 Copy of Manufacturing License: A valid copy of license to manufacture for Sale or for Distribution of Medical Devices issued by the CLA or SLA, as the case may be.

4.5 Legal Undertaking by the manufacturer shall be submitted on a 100 Rupees registered notarized stamp (recently notarized) by the manufacturer 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 FSC may not be granted for the product(s) that are meant exclusively for export purposes. Hence, the applicant needs to ensure that such products are not included in the application for FSC.
2. Please refer **Annexure B** for the checklist of documents to be submitted with the FSC application.
3. The FSC issued by the Licensing Authority is valid upto the validity of the manufacturing license, provided no regulatory action has been initiated by the Licensing Authority on the applied products.

Reference Documents:

1. The Medical Devices Rules, 2017 published in the Official Gazette by Government of India vide G.S.R. 78(E) dated 31.01.2017.
2. Gazette notification published in the Official Gazette by Government of India vide G.S.R. 318(E) dated 18.04.2019.

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 Free Sale Certificate (FSC) for the products, as mentioned below, licensed under the valid manufacturing license number _____ (**manufacturing 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 FSC:

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 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 FREE SALE CERTIFICATE (FSC) APPLICATION

S. No.	Checklist
1.	Cover letter
2.	Application for FSC
3.	Fee challan receipt
4.	A copy of valid Manufacturing license (along with retention application file number for all applied products, if applicable)
5.	Legal Undertaking on 100 Rupees registered notarized stamp (recently notarized) from the manufacturer 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