Central Drugs Standard Control Organization

(Medical Devices Division)

Guidance Document

Title: Guidance Document for obtaining Free Sale Certificate for licensed Medical devices in India

Doc No.: CDSCO/MD/GD/FSC/01/2024

1. **PURPOSE:** To provide guidance to Indian manufacturers for submission of application to the Licensing Authority for obtaining Free Sale Certificate 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 or State Licensing Authority as the case may be, by the manufacturer, having a valid License to manufacture for sale or for distribution of Medical Devices obtained under the Medical Devices Rules, 2017.

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 Bharatkosh challan receipt: The **requisite fees** prescribed in the Second Schedule of the Medical Devices Rules, 2017 for Free Sales Certificate to export medical device shall be paid through the online Bharatkosh challan by the applicant, at the rate of 1000 INR per category of medical device.

4.3 A valid copy of **license to manufacture** for Sale or for Distribution of Medical Devices along with approved product list issued by State Licensing Authority or Central licensing Authority, as the case may be.

4.4 Legal undertaking by the manufacturer stating that no action has been initiated against firm due to adverse events, market complaint and Not of Standard Quality (NSQ) report of any product in India on one hundred rupees non-judicial notarized stamp paper.

Note:

1. For Class A and Class B medical devices, manufacturers are requested to contact respective State Licensing Authority for issuance of Free Sale Certificate.

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.