Guidance Document

(Medical Device and Diagnostic Division)

Title: Guidance Document on Free Sale Certificate of Notified Medical Devices in India

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

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

GUIDANCE DOCUMENT ON FREE SALE CERTIFICATE OF NOTIFIED MEDICAL DEVICES

1. **PURPOSE:** To provide guidance to Indian manufacturers for submission of application for Free Sale Certificate to Central Licensing Authority (CDSCO) Authority.

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

3. **Mode of Submission:** Offline (Hard copy)

4. **GUIDANCE:**

An application shall be made to the Central Licensing Authority (CDSCO) for Class C & D medical devices by the manufacturer, having a valid License to manufacture for sale or for distribution of notified Medical Devices.

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 The **requisite fees** prescribed in second schedule of Medical Devices Rules 2017 for Certificate to export medical device. The Applicant shall make a payment of 1000 INR for obtaining Free Sale Certificate for each category of medical device through online Bharatkosh challan.

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 List of products for which the Free Sale Certificate is required.

4.5 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 & B medical devices, manufacturers are requested to contact respective State Licensing Authority for issuance of Free Sale Certificate.**
2. **For other than notified medical devices Free Sale Certificate is issued by Directorate General of Foreign Trade, Ministry of Commerce and Industry Udyog Bhawan, H-Wing, Gate No. 2, Maulana Azad Road, New Delhi – 110011**

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.**