

No.29/MISC/3/2015-DC(290)
Dte. General of Health services
Office of Drugs Controller General (India)
FDA Bhawan, Kotla Road, New Delhi-110002

Date:

21 APR 2016

To,

All state /UT Drugs controllers,

Subject: Extending the validity of Free Sale Certificate for notified medical devices till the expiry of manufacturing licence for export purpose- Reg.

Sir,

Under the provisions of Drugs & Cosmetics Act, notified medical devices are regulated as "Drugs" under section 3(b)(iv). At present, only 15 medical devices are notified and regulated for its import, manufacture and market in the country under the said Act & Rules. A Free Sale Certificate (FSC) with the validity of two years is issued to the manufacturer by the concerned State Licensing Authority (SLA) for export purpose.

A concern was raised by Medical Devices Associations at various forums from time to time to extend the validity of FSC for such notified medical devices till the expiry of the manufacturing license granted to the manufacturer. In order to address the concern, it was decided in the meeting held in Ministry of Health & family Welfare, New Delhi that in order to promote the export from the country, the State Licensing Authority may issue Free Sale Certificate to the manufacturer with the validity of their manufacturing license.

In view of the above, in order to bring uniformity in its implementation, you are requested to grant FSC to the manufacturer located under your jurisdiction with the validity of their manufacturing license to promote export from the country.

You may also charge a fee of Rs. 5000/- per application from the manufacturer for issuing of such certificate.

Yours faithfully,


(Dr. G. N. Singh)
Drugs Controller General (I)

Copy to:

1. PPS to JS (R), Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi
2. All DDC (I) of Zonal offices of CDSCO
3. Industry Associations-CII, FICCI, AIMED, ADMI, IDMA, ASSOCHAM
4. CDSCO Website