



REGISTRATION CERTIFICATE FOR SELLERS & DISTRIBUTORS OF MEDICAL DEVICES

This is to bring to the notice of all members - with reference to the Ministry of Health & Family Welfare's notification no. G.S.R 104(E) containing Draft Rules for amendments to the Medical Devices Rules dated 9th Feb 2022 –

A series of amendments have been proposed through which a '**Registration Certificate to sell, stock, exhibit or of offer for sale or distribute a medical device including in vitro diagnostic medical device**' has been introduced. This will come into effect at least after 45 days from the date of the notification and through further announcements by the Ministry.

In a nutshell, **this Registration Certificate will replace the Drug License requirement** for Dealers and Distributors of Medical Devices. The Registration Certificates will have to be applied for, and will be issued by the state licensing authorities.

It is indeed a moment of pride for all SMTA members that our association's consistent efforts and representations to various departments and the Ministry have paid off. Following our submissions to the departments regarding 'Drug Licensing' for traders through our letters and subsequent meetings with the various authorities - our suggestions have been taken into consideration and these changes have been implemented.

We are confident that this is in the interest of traders and will benefit all SMTA members as well as all the sellers and distributors of Medical Devices in India, bringing ease to the process and eliminating the need for drug licenses.

We request you to go through the notification and for any queries please contact the SMTA Office Bearers.

We will be further communicating the objections & suggestions of our members to simplify the registration process further, as we feel it can be improved. Our efforts will focus on including these suggestions before the notification comes into effect.

Thanking You,
Regards,

Pradeep Chawla
President

The Surgical Manufacturers & Traders Association