F. No. 29/Misc/03/2022-DC (269)
Central Drugs Standard Control Organisation
Government of India
Ministry of Health and Family Welfare
****

FDA Bhawan, New Delhi
Dated the 21st October, 2022

NOTICE

Subject: Implementation of Gazette notification vide G.S.R 754(E) dated 30.09.2022 - Regarding.

The Ministry of Health and Family Welfare, Government of India has published Medical Devices (fifth amendment) Rules, 2022 vide G.S.R 754(E) dated 30.09.2022, wherein provision for Registration Certificate to sell, stock, exhibit or offer for sale or distribute a medical device including *in vitro* diagnostic medical device, as alternative to Drugs Sale License has been implemented with effect from 30.09.2022.

Various representations have been received from stakeholders, regarding implementation of said rules stating that their application in hard copy is not being accepted. As per the said rules, the applicant may apply for grant of Registration Certificate in Form MD-41 to the concerned State Licensing Authority (SLA) and the SLA after satisfying the requirements shall issue Registration Certificate in Form MD-42 to sell, stock, exhibit or offer for sale or distribute a medical device including *in vitro* diagnostic medical device in the country.

Accordingly, all the SLAs are requested to accept the applications in hard copy from such applicants of medical devices and dispose off the application expeditiously on priority and also to ensure uninterrupted access/supply of such medical devices.

VGS

(Dr V. G. Somani)
Drugs Controller General (I)

To

All State/ UTs Drugs Controllers

Copy to:

1. All Stakeholders/Associations of Medical Devices & In vitro Diagnostics.
2. All Zonal/Sub-Zonal offices of CDSCO
3. All Port offices of CDSCO

Copy for information to:

PS to DGHS
PS to JS(R)