

Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
Medical Device and Diagnostic Division

Food and Drug Administration Bhawan
Kotla Road, New Delhi-110002

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Office Memorandum

SUB: -Clarification – for import of “Pre filled Syringes Components”– Barrels (without Needle only), Plunger rod and stopper in unassembled form – Reg.

This office has received letters from importers and port offices of the CDSCO seeking the clarification on subject mentioned product.

It is hereby clarified that “Pre filled Syringes Components”– Barrels (without Needle only), Plunger rod and stopper in unassembled form are not regulated under Drugs and Cosmetics Act 1940.

However “Pre filled Syringes Components”– Barrels (with Needle) is regulated under Drugs and Cosmetics Act 1940.

This clarification is issued for compliance and to maintain uniformity.


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

To,
All the Port /Zonal/Sub-zonal offices of CDSCO