

No. 29/Misc/03/2020-DC(89)  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
(Medical Devices Division)

FDA Bhawan, Kotla Road,  
New Delhi, Dated 19/6/2020

To,

All Zonal/ Sub- Zonal/ Port Offices of CDSCO

Sub: - Clarification regarding import of diagnostic kits/ reagents for Research Use Only (ROU) for academic research purpose.

Sir,

This is with reference to the subject cited above.

In this regard, it is to clarify that the products meant for "Research Use Only" to be used in academic research institutions and not meant for any diagnostic or therapeutic purpose are not being regulated under provisions of Drugs & Cosmetic Act and Medical Devices Rule there under. This is already clarified through FAQ Q. No. 17 Document no. CDSCO/IVD/FAQ/02/17 published in CDSCO website and letter of this office vide no. 29/Misc/3/2012-DC(09) dated 13/07/2012 (Copy enclosed).

However, the applicant needs to submit an undertaking in this regard at the concerned port office of CDSCO stating that the imported products shall be used by the research institution for academic research purpose only and shall not be used for any in-vitro diagnostic/ therapeutic purpose in diagnostic labs/ hospitals. Such products shall be labelled as "for research use only".

Yours faithfully,



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