No. 29/Misc/03/2020-DC (60)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Medical Devices and Diagnostics Division)

FDA Bhawan, Kotla Road
New Delhi – 110 002
Dated: 23/4/2020

NOTICE

Subject: Submission of notarized/ apostilled documents for Import of medical devices and in-vitro diagnostic kits in view of COVID 19 - reg.

This office has received representation about difficulties in submission of notarized, apostilled regulatory documents such as Power of Attorney, QMS certificate, Free Sale Certificate etc. for applications for Import of medical devices and in-vitro diagnostic kits under Medical Devices Rules, 2017 due to COVID-19 pandemic.

The matter has been examined carefully in view of the situation due to COVID-19 outbreak and it has been decided that the applicant may submit applications for import licence as per the provisions of Medical Device Rules, 2017 along with such documents which are self attested and an undertaking that they will submit the notarized/ apostilled documents after obtaining the same from the concerned authority after normalization of the situation in light of COVID-19 or within four months whichever is earlier.

Such applications, as and when received, will be processed and, if found satisfactory, import licence may be issued with the condition that the firm shall submit notarized/ apostilled documents obtaining the same from the concerned authority after normalization of the situation in light of COVID-19 or within four months whichever is earlier.

V.G.S

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

To,

All Stakeholders through CDSCO website.