**F. No.29/Misc/03/2019-DC(180)**
**Government of India**
**Directorate General of Health Services**
**Central Drugs Standard Control Organization**
**(New Drugs Division)**

FDA Bhawan, Kotla Road
New Delhi.-110002
Dated: 15 NOV 2019

**OFFICE MEMORANDUM**

**Subject: Processing of application for product approved as medical device in the country of origin, but covered under the definition of drug in the country - Regarding**

CDSCO receives applications for grant of permission to import various products falling under definition of drug/new drug, but approved as medical device in the country of origin and not covered under the medical devices notified in the country.

In order to streamline the process, it has been decided that processing of such applications will be done by New Drugs division / Import division of CDSCO and accordingly, applications should be submitted through SUGAM Portal. However the CMC, safety & efficacy data, etc of the product should be submitted as per the checklist applicable for medical devices.

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

To,

1. CDAC with a request to make provision for above in the sugam portal
2. All Stakeholders through website of CDSCO
3. Zonal/Sub-Zonal offices of CDSCO
4. All officers of CDSCO (HQ)
5. Guard file