

No. 29/MISC/3/2018-DC (165)
Government of India
Directorate General of Health Services
Ministry of Health & Family Welfare
Central Drugs Standard Control Organisation
(Medical Devices Division)

Date: 8/11/2019

Notice

It is brought to the notice of this office during the meeting of stakeholders of Medical Devices held on 15.10.2019 that an exemption from Drugs sale license (20B & 21B) for the import of high tech equipments like X-ray, MRI, PET, Ultrasound, CT Scan etc. under MDR-2017 is required.

The importers of such equipments need to maintain all records of transactions, installations, maintenance, agreements etc. Accordingly, proposal will be officially moved to DTAB for exemption from Drugs Sale License for such equipments under MDR-2017.

All stakeholders are requested to forward their comments at e-mail id: ddcimd-cdsco@nic.in.

V.G.S

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