

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

Various Stakeholders of Medical Devices have raised a concern regarding the clarification with respect to Implantable Medical Device.


In this regard, it is requested to refer the Fifth Schedule (Clause 3.5) of Medical Devices Rules, 2017 as under:

“Implantable Medical Device. - Medical Device intended:-

(a) to be totally or partially introduced into the human or animal body or a natural orifice; or

(b) to replace an epithelial surface or the surface of the eye; by surgical intervention, and which is intended to remain after the procedure for at least thirty days, and which can only be removed by medical or surgical intervention.”

All Implantable Devices will be regulated with effect from 01.04.2020 as per gazette notification dated 08.02.2019.


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