

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 have sought a clarification regarding the environmental conditions for the equipments which are to be regulated from 01.01.2020 and 01.04.2020.

In this regard, it is to clarify that the environmental conditions referred in fifth schedule, annexure 'A' of Medical Devices Rules, 2017 ~~for condoms~~ such as well ventilated area with neat and clean environment, free from dust and other particulate matter, air conditioning will be applicable for such equipments.

A proposal will be moved to DTAB, State bodies are requested to send their comment on ddcind-edsc@nic.in

V.G.

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