

F.No.X.11035/281/2018-DRS
Government of India
Ministry of Health and Family Welfare
(Department of Health & Family Welfare)
(Drugs Regulation Section)

Nirman Bhawan, New Delhi
Dated 18th October, 2019


NOTICE

Subject: Draft notification to notify all the medical devices under sub-section (b) of section 3 of the Drugs and Cosmetics Act, 1940 to regulate them as per the provisions of the Act and Medical Devices Rules, 2017 thereunder - regarding.

Ministry of Health and Family Welfare, Government of India proposes to notify all the medical devices under sub-section (b) of section 3 of the Drugs and Cosmetics Act, 1940 to regulate them as per the provisions of the said Act and Medical Devices Rules, 2017 framed thereunder. In this regard, a notification has been prepared, a copy of which is enclosed.

2. It has been decided to solicit suggestions/comments/objections from the public/stakeholders with regard to the said draft notification before its finalization. The suggestions/comments/objections may be forwarded within 30 days from the date of issue of this Notice by email at drugsdiv-mohfw@gov.in or by post to Under Secretary (Drugs Regulation), Ministry of Health and Family Welfare, Room No. 414A, D Wing, Nirman Bhawan, New Delhi – 110011. Only the suggestions/comments/objections received on the above email/address within the period of 30 days shall be taken into consideration for finalization of the notification.

Encl: Draft Notification


(R. G. Singh)
Under Secretary to the Govt. of India
Tele: 2306 3019

**[To be published in the Gazette of India, Extraordinary,
Part II, Section 3, Sub-section(ii)]**

**Ministry of Health and Family Welfare
(Department of Health and Family Welfare)**

Notification

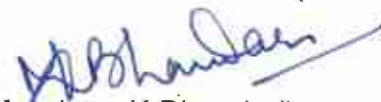
New Delhi, the 19th October, 2019.

S.O. —(E).- In pursuance of sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby specifies the following devices intended for use in human beings or animals as drugs with effect from the 1st day of December, 2019, namely:-

All devices including an instrument, apparatus, appliance, implant, material or other article; whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of -

- (i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
- (ii) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;
- (iii) investigation, replacement or modification or support of the anatomy or of a physiological process;
- (iv) supporting or sustaining life;
- (v) disinfection of medical devices; and
- (vi) control of conception.

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(Dr. Mandeep K Bhandari)

Joint Secretary to the Government of India.