

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 18th 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.

[F.No. X.11035/281/2018-DRS]


(Dr. Mandeep K Bhandari)

Joint Secretary to the Government of India.

[भारत के राजपत्र, असाधारण, भाग 2, खंड 3, उपखंड (ii) में प्रकाशनार्थ]

स्वास्थ्य और परिवार कल्याण मंत्रालय
(स्वास्थ्य और परिवार कल्याण विभाग)

अधिसूचना

नई दिल्ली, तारीख 13th अक्टूबर, 2019

का.आ.____ (अ).-- केंद्रीय सरकार, ओषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 3 के खंड (ख) के उप-खंड (iv) के अनुसरण में, ओषधि तकनीकी सलाहकार बोर्ड के साथ परामर्श के पश्चात् तारीख 1 दिसंबर, 2019 से मानव या पशुओं में उपयोग करने के लिए आशयित निम्नलिखित युक्तियों को ओषधि के रूप में विनिर्दिष्ट करती है, अर्थात:-

उपकरण, साधित्र, साधन, इम्प्लांट, सामग्री या अन्य वस्तुओं को सम्मिलित करते हुए सभी युक्तियां; चाहे अकेले या समिश्रण के रूप के प्रयोग की जाती है, जिसके अंतर्गत साफ्टवेयर या उपसाधन भी है, उसके विनिर्माता द्वारा उनका विशिष्टतः मानवों या पशुओं के लिए प्रयोग किया जाना आशयित है जो किसी भेषजगुणविज्ञानीय या प्रतिरक्षाविज्ञानीय या चयापचय साधनों द्वारा मानव शरीर या पशुओं में या पर प्राथमिक आशयित क्रिया नहीं करता है, लेकिन जो निम्नलिखित एक या अधिक विनिर्दिष्ट प्रयोजनों के लिए ऐसे साधनों द्वारा आशयित कृत्यों में सहायता करेंगे-

- (i) किसी रोग या विकार का निदान, निवारण, मानीटरी, उपचार या उपशमन;
- (ii) किसी क्षति या अशक्तता का निदान, मानीटरी, उपचार, उपशमन या उसके लिए सहायता;
- (iii) शरीर रचना विज्ञान या शारीरिक प्रक्रिया का अनुसंधान, प्रतिस्थापन या उपांतरण या सहयोग;
- (iv) जीवन समर्थक या संपोषक;
- (v) चिकित्सा युक्तियों का विसंक्रामण; और
- (vi) गर्भधारण का नियंत्रण।

[फा.स. एक्स-11035/281/2018-डीआरएस]

मनदीप भंडारी

(डॉ मनदीप के भंडारी)

संयुक्त सचिव, भारत सरकार