

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1. Member to Agreement notifying: <u>INDIA</u> If applicable, name of local government involved (Articles 3.2 and 7.2):
2. Agency responsible: Ministry of Health and Family Welfare Name and address (including telephone and fax numbers, e-mail and web-site addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: Assistant Director General (PFA), Directorate General of Health Services, Nirman Bhavan, New Delhi – 110011; Tel: 23062290; E-mail: adgpfa@nb.nic.in Website of the Ministry of Health & Family Welfare, Government of India: http://www.cdsc.nic.in/
3. Notified under Article 2.9.2 [], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): i) Cardiac Stents, (ii) Drug Eluting Stents, (iii) Catheters, (iv) Intra Ocular Lenses, (v) I. V. Cannulae, (vi) Bone Cements, (vii) Heart Valves, (viii) Scalp Vein Set, (ix) Orthopaedic Implants, (x) Internal Prosthetic replacements
5. Title, number of pages and language(s) of the notified document: The sub-clause (iv) of clause (b) of Section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940), Notification no. S.O. 1468 (E) – dated 6 October 2005 & G.S.R. 627(E) – 7 October, 2005 (1 page each, English and Hindi).
6. Description of content: Vide these notifications, the above items mentioned in serial number 4 above have been considered as drugs and the production and sale or distribution of these drugs would be under Central License Approving Authority.
7. Objective and rationale, including the nature of urgent problems where applicable: To develop suitable mechanism to regulate import as well as manufacture of medical devices of critical nature.
8. Relevant documents: The Drugs and Cosmetics Rules, 1945

9.	Proposed date of adoption: Proposed date of entry into force:	}	Already in force.
10.	Final date for comments:		
11.	Texts available from: National enquiry point [] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:		
	Assistant Director General (PFA), Directorate General of Health Services, Nirman Bhavan, New Delhi – 110011; Tel: 23062290; E-mail: adgpfa@nb.nic.in Website of the Ministry of Health & Family Welfare, Government of India, http://www.cdsc.nic.in/		