

29/Misc./5/2014-DC
Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
(Medical Device and Diagnostic Division)

Food & Drugs Administration Bhawan,
Kotla Road, New Delhi-110002

Date: 09.07.2014

Office Order

Sub: Clarification for regulation of medical devices under the provision of Drugs and Cosmetics Act and Rules thereunder- regarding

The following categories of medical devices were notified by the Ministry of Health and Family Welfare through Gazette notification mentioned hereunder to be considered as Drug under Section 3 clause (b), sub clause (iv) of the Drugs and Cosmetics Act, 1940:-

S. No.	Name of the Device	Notification Number	Date of notification
1.	Disposable Hypodermic Syringes	GSR 365 (E)	17.03.1989
2.	Disposable Hypodermic Needles	GSR 365 (E)	17.03.1989
3.	Disposable Perfusion Sets	GSR 365 (E)	17.03.1989
4.	In Vitro Diagnostic Devices for HIV, HBsAg and HCV	GSR 601 (E)	27.08.2002
5.	Cardiac Stents	S.O. 1468 (E)	06.10.2005
6.	Drug Eluting Stents	S.O. 1468 (E)	06.10.2005
7.	Catheters	S.O. 1468 (E)	06.10.2005
8.	Intra Ocular Lenses	S.O. 1468 (E)	06.10.2005
9.	I.V. Cannulae	S.O. 1468 (E)	06.10.2005
10.	Bone Cements	S.O. 1468 (E)	06.10.2005
11.	Heart Valves	S.O. 1468 (E)	06.10.2005
12.	Scalp Vein Set	S.O. 1468 (E)	06.10.2005
13.	Orthopaedic Implants	S.O. 1468 (E)	06.10.2005
14.	Internal Prosthetic Replacements	S.O. 1468 (E)	06.10.2005

It is hereby clarified that any devices other than above do not require any registration, licence, permission or NOC for their import or manufacture, sale and distribution so far as the provisions of the Drugs and Cosmetics Act and Rules made thereunder are concerned.


(Dr. G. N. Singh)
Drugs Controller General (I)

To

1. All State Drugs Controller
2. Zonal / Sub-Zonal/Port officers of CDSCO.

Copy forwarded to:

Medical Devices Associations

Copy to:

Joint Secretary (R)

Note: In case of any further specific queries that the office of DCG(I) or the deputy Drugs Controller (I) i/c of Medical devices may be consulted through post or email at ddcimd-cdsco@nic.in.

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