Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare

Food and Drug Administration Bhawan
Kotla Road, New Delhi-110002

No. 29/Misc./3/2009-DC

Dated 05/March/2012

To,

All State Drugs Controllers

Subject: Regulation of import and manufacture of certain Medical Devices covered under the categories of notified medical devices-reg

Sir,

The proposal of regulation of certain medical devices which were considered to be covered under the categories of notified devices under the Drugs and Cosmetics Rules notified under the Gazette Notifications GSR 365(E) dated 17.03.1989 and S.O. 1468(E) dated 6.10.2005 under the Drugs and Cosmetics Act was considered in the 60th meeting of DTAB held on 10.10.2011.

It may be stated that the office of DCG (I) had earlier prepared a list of certain medical devices which were considered to be covered under categories of the already notified devices. The matter was examined by an Expert Committee on medical devices which recommended that the following devices may be regulated under already notified medical devices as under.

S.No.	Name of Devices	Class of Notified Devices
1.	Spinal Needle	Disposable Hypodermic Needle
2.	Insulin Syringes	Disposable Hypodermic Syringes
3.	Three Way Stop Cock as an accessory of I.V. Cannula/Catheter/Perfusion Set	Disposable Perfusion Set
4.	Introducer Sheath	I.V. Cannula
5.	Cochlear Implant	Internal Prosthetic Replacement
6.	Close Wound Drainage Set	Catheter
7.	AV Fistula Needle	Disposable Hypodermic Needle

(20)

8	Extension Line as an accessory of Infusion Set	Disposable Perfusion Set
9.	ANGO kit/PTCA /Cath Lab Kit	I.V. Cannula/ Disposable Perfusion Set
10.	Measure Volume Set	Disposable Perfusion Set
11	Flow Regulator as an accessory of Infusion Set	Disposable Perfusion Set

The DTAB after deliberations agreed to the recommendations of the Expert Committee for regulation of the quality of these devices under the already notified devices.

In view of the above, it is stated that the above medical devices are considered as drugs for the purpose of their regulation under section 3 (b) (iv) of Drugs and Cosmetics Act, 1940 and Rules made thereunder.

Yours Faithfully

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

Copy for information and necessary follow up to:-

1. All Zonal/ Sub-zonal/Port offices of CDSCO

GOVERNMENT OF RAJASTHAN
DRUGS CONTROL ORGANISATION, SWASTHYA BHAWAN,
TILAK MARG, JAIPUR, RAJASTHAN

No. DC/D-2/Volume-III/Amand-2/2012/ 175 Date:- 25/04/2012

Copy Forwarded to:-

1. All Asstt. Drugs Controller, Rajasthan State
2. Members of Formulation Committee, Hqrs.
3. President, Rajasthan Pharmaceutical Manufacturer, Association Jaipur for circulation amongst its members C/o M/s JPW, SP-1, 22 Godawn Ind. Estate, Jaipur.
4. Dy. Director, Drugs Testing Laboratory, Sethi Coloney, Jaipur
5. Gard File.

Drugs Controller
Rajasthan Jaipur