


LIST OF NOTIFIED MEDICAL DEVICES

The Ministry of Health and Family Welfare, Govt. of India under following Gazette notifications has notified the following devices to be considered as drugs under Section 3, Clause (b) . Sub clause (iv) of the Drugs and Cosmetics Act: -

| 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 |

Note: Further, the following products are regulated as 'Drugs' under Drugs & Cosmetics Act & Rules there under: -

1. Blood Grouping Sera
2. Ligatures, Sutures and Staplers
3. Intra Uterine Devices (Cu-T)
4. Condoms
5. Tubal Rings
6. Surgical Dressings
7. Umbilical Tapes
8. Blood/Blood Component Bags


20-11-2010
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