

REGULATORY STATUS OF MEDICAL DEVICES IN INDIA

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- **DEFINITION OF MEDICAL DEVICES**
- **DEVICES ARE REGULATED THROUGH DRUGS & COSMETICS ACT 1940 AND RULES THEREUNDER**
- **NOTIFIED MEDICAL DEVICES**
 1. **STERILE DISPOSABLE PERFUSION SETS FOR SINGLE USE ONLY.**
 2. **STERILE DISPOSABLE HYPODERMIC SYRINGES FOR SINGLE USE ONLY.**
 3. **STERILE DISPOSABLE HYPODERMIC NEEDLES FOR SINGLE USE ONLY.**
 4. **IN VITRO DIAGNOSTIC DEVICES FOR HIV, HbSAg & HCV.**

GMP REQUIREMENT FOR MEDICAL DEVICES

**SCHEDULE M III OF DRUGS & COSMETICS ACT
PRESCRIBES THE GMP.**

DEVICES REGULATED AS DRUG

- **INTRA UTERINE DEVICES**
- **CONDOMS**
- **SUTURES**
- **COTTON BANDAGES**

STANDARDS

- **BUREAU OF INDIAN STANDARDS FOR IUDs, DISPOSABLE SYRINGES & SETS**
- **SCHEDULE R FOR CONDOMS**

DIAGNOSTIC KITS

- **CRITICAL DIAGNOSTIC KITS**
- **NON CRITICAL DIAGNOSTIC KITS**
- **REGULATORY REQUIREMENT FOR IMPORT**
- **REGULATORY REQUIREMENT FOR MANUFACTURE**
- **REGISTRATION OF FOREIGN MANUFACTURERS FOR CRITICAL KITS & OTHER DEVICES**

THANK YOU