# MEDICAL DEVICES

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Medical devices range from simple tongue depressors and bedpans to complex programmable pacemakers with micro-chip technology and laser surgical devices. The biomedical devices consist of 900 products grouping covering 50 clinical specializations and can be broadly classified into diagnostics ,therapeutics and monitoring devices.

Medical devices are different from drugs and their biological evaluation requires a different approach. If the primary intended use of the product is achieved through chemical action or by being metabolized by the body, the product is usually a drug.

A medical device according to FDA is:

"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

International standard ISO 10993-1:2003 Part 1 categorizes medical devices according to the nature and duration of body contact.

**A. Categorization by nature of body contact**

**1) Non contacting devices**

Medical devices that do not contact the patient's body directly or indirectly.

**2) Surface contacting devices**

These include medical devices in contact with the following surfaces:

a) Skin: Devices that contact intact skin surfaces only; e.g. electrodes, external prostheses, fixation tapes, compression bandages and monitors of various types.

b) Mucosal membranes: Devices that contact intact mucosal membranes e.g. contact lenses, urinary catheters, intra vaginal & intra intestinal devices (stomach tubes, sigmoidoscopes, colonoscopes, and gastro scopes), endotracheal tubes, bronchoscopes, dental prostheses, orthodontic devices and intrauterine devices.

c) Breached or compromised surfaces: Devices that contact breached or otherwise compromised body surfaces e.g. dressings, healing devices and occlusive patches for ulcers, burns and granulation tissue.

3) External communicating devices

These include the devices in contact with the following application sites:

a) Blood path, indirect: Devices that contact the blood path at one point and serve as a conduit for entry into the vascular system e.g. solution administration sets, extension sets, transfer sets and blood administration sets.

b) Tissue/bone/dentin: Devices that contact tissue, bone or pulp/dentin systems; e.g. laparoscopes, arthroscopes, draining systems, dental cements, dental filling materials and skin staples.

c) Circulating blood: Devices that contact circulating blood; e.g. intravascular catheters, temporary pace maker electrodes, oxygenators, extracorporeal oxygenator tubing and accessories, dialysers, dialysis tubing and accessories, haemoadsorbants and immunoadsorbants.

**4) Implant devices**

These include medical devices in contact with the following application sites:

a) Tissue/bone :

a. Devices principally contacting bone: eg orthopaedic pins, plates, replacement joints, bone prostheses, bone cements and intraosseous devices.

b. Devices principally contacting tissue and tissue fluid; eg pacemakers, drug supply devices, neuromuscular sensors, and stimulators, replacement tendons, breast, implants, artificial larynxes, subperiosteal implants and ligation clips.

b) Blood: Devices principally contacting blood; eg pacemaker electrodes artificial arteriovenous fistulae, heart valves, vascular grafts, internal drug delivery catheters and ventricular assist devices.

B. Categorization by duration of contact.

a) Limited exposure (A): Devices whose single, multiple use or contact is likely to be up to 24 h.

b) Prolonged exposure (B): Devices whose single, multiple or long term use or contact is likely to exceed 24 h but not 30 days.

c) Permanent contact (C): Devices whose single, multiple or long term use or contact exceeds 30 days.

Materials like synthetic or natural polymers, metals, alloys, ceramic or nonviable substance including tissues rendered non viable shall be used as a medical device or any part thereof.

Human drugs in United States are regulated by FDA's Center for Drug Evaluation and Research (CDER). Biological products which include blood and blood products, and blood banking equipment are regulated by FDA's Center for Biologics Evaluation and Research (CBER). FDA's Center for Veterinary Medicine (CVM) regulates the manufacture and distribution of food additives and drugs that will be given to animals. These include animals, from which human foods are derived, as well as food additives and drugs for pet (or companion) animals. CVM is responsible for regulating drugs, devices, and food additives given to, or used on, over one hundred million companion animals, plus millions of poultry, cattle, swine, and minor animal species. (Minor animal species include animals other than cattle, swine, chickens, turkeys, horses, dogs, and cats.)

The Medicines and Healthcare products Regulatory Agency (MHRA) regulates medical devices in the UK under European legislation.

Currently, India does not regulate the sale of medical devices. India accepts non-U.S. Food & Drug Administration-approved as well as non-CE-marked medical devices (however, in accordance with U.S. FDA requirements, U.S. manufacturers may only export to India and to other countries medical devices that have been approved either by the USFDA or another FDA-designated "Tier-1" country, i.e., Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, or any member nation in the European Union or the European Economic Area).

Under India's Ministry of Health and Family Welfare, the Department of Health has nominal jurisdiction over medical device regulation, and reportedly is considering the introduction of a separate regime of regulations for medical devices (currently, the Ministry regulates pharmaceuticals under authority of India's Drug and Cosmetics Act, and pharmaceuticals must be specifically registered in order to be sold in India).

The Ministry of Health (MOH) issued a notification to regulate, with immediate effect, 10 categories of medical devices. As of 6 October 2005, medical devices in each of these categories will be regulated as a "Drug". The categories are 1.Cardiac Stents, 2.Drug Eluting Stents, 3.Catheters, 4. Intra Ocular Lenses, 5 I.V. Cannulae, 6.Bone Cements, 7.Heart Valves, 8.Scalp Vein Set, 9.Orthopedic Implants, 10. Internal Prosthetic Replacements.

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