

What is "Medical Device"?

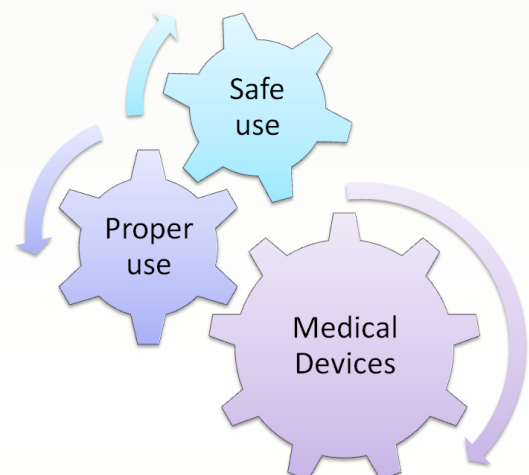
Why should I know about "Medical Device"?

- Medical devices have all along played an important part in healthcare. As technology advances, an increasing number of medical devices are available for use and they are becoming more and more user-friendly. Some medical devices can now be used at home by the general public. In our daily lives, when we look around, medical devices are frequently encountered.
- The use of unsafe devices or improper use of devices may affect the health of patients, users or other persons. Therefore, we should know them well in order to ensure proper and safe use of medical devices.

What does "Medical Device" include?

- "Medical Device" covers a broad variety of products. It generally refers to any instrument, apparatus, appliance, material or other articles (excluding drugs) that are designed and manufactured to be used for human beings for one or more medical purposes including the following:
 - Diagnosis, prevention, treatment or monitoring of diseases ;
 - Diagnosis, treatment or monitoring of an injury, or compensation for an injury;
 - Supporting or sustaining life;
 - Investigation, replacement, modification or support of body structure or function;
 - Providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body;
 - Control of conception including contraception;
 - Disinfection of medical devices.

- Whether a product is a medical device depends on the precise claims made by the manufacturer, its intended use, etc.



How are "Medical Devices" classified?

- There are two types of "Medical Devices", **General Medical Devices** and **In Vitro Diagnostic (IVD) Medical Devices**.

General Medical Devices are classified into four classes according to their risk to patients, users and other persons.

Class	Risk Level	Examples for reference
I	Low	Stethoscope, Bandages, Wheelchairs, Walking aid, Compression hosiery
II	Low-moderate	Electrocardiograph (ECG), Transcutaneous electrical neuromuscular stimulator (TENS), Hearing aids, Electronic blood pressure monitor, Urinary catheter
III	Moderate-high	Contact lens care solutions, Diagnostic X-ray machines, Automated external defibrillator, Insulin pen, Prosthetic joint
IV	High	Artificial heart valves, Implantable cardiac pacemakers, Neuro-endoscopes, Breast implant

In Vitro Diagnostic (IVD) Medical Devices are also classified into four classes according to their risk to individuals and public health.

Class	Risk Level	Examples for reference
A	Low	Plain urine cup, Identification kits for cultured microorganism
B	Low-moderate	Urine test strips, Pregnancy test kits
C	Moderate-high	Home use blood glucose meters and their test strips, Screening test for Spina Bifida in foetus, Diagnostic assay for Chlamydia pneumonia
D	High	Tests to detect Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV)

- While the risk levels of different medical devices may vary, users should not take it lightly and must use all classes of medical devices in a proper and safe manner.
- Please visit our website for more classified examples of **General Medical Devices** and **In Vitro Diagnostic (IVD) Medical Devices**.

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