

How are "Medical Devices" classified?

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

Class	Risk Level	Examples
I	Low	Bandages, Wheelchairs
II	Medium-Low	Hearing aids, Electronic sphygmomanometers
III	Medium-High	Contact lens care solutions, Diagnostic X-ray machines
IV	High	Artificial heart valves, Implantable cardiac pacemakers

For more information, please visit our website or call our office.

Website: www.mdco.gov.hk

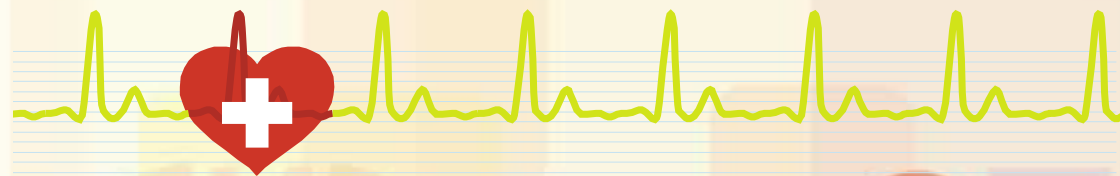
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Medical Device Control Office

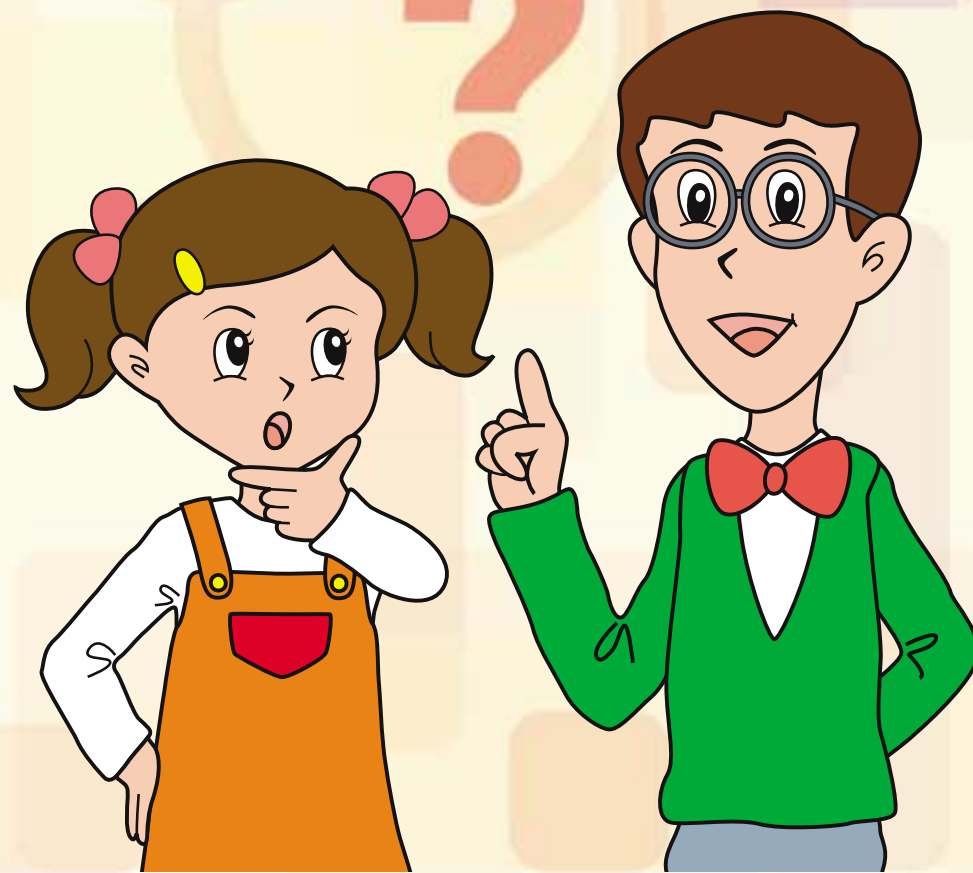
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Department of Health



What is "Medical Device"



Why should I know about "Medical Device"?

Are these Medical Devices?

Why should I be concerned about Medical Devices?

Medical devices often play an important role in our healthcare processes. As technology advances, more and more medical devices are available for use and they are becoming more user-friendly. Some medical devices can even be used at home. In our daily lives, when we look around, medical devices are frequently encountered actually.

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 use of safe 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) used for human beings for purposes including the following:

- Diagnosis, prevention, treatment or monitoring of diseases and / or injuries;
- Rehabilitation;
- 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.

X-ray Machines

Cardiac Pacemakers

Blood Glucose Meters

Wheelchairs

These are all "Medical Devices"!



Whether a product is a medical device depends on the manufacturer's intended use.