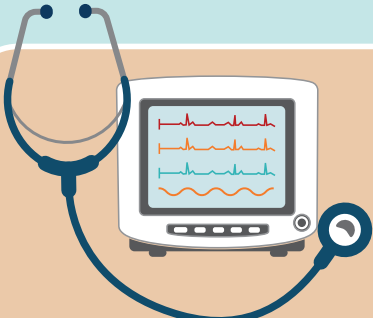


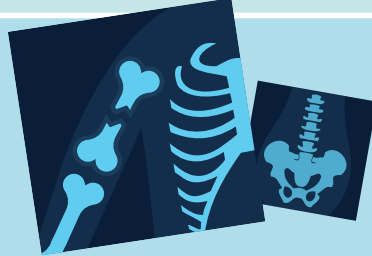
醫療儀器 MEDICAL DEVICES

醫療儀器泛指製造商擬用作以下醫療用途的非藥物產品：

Medical devices generally refer to non-pharmaceutical products intended by manufacturers for the following medical purposes:



診斷、預防、治療或
監察疾病
Diagnosis, prevention, treatment
or monitoring of diseases



診斷、治療或監察傷勢或
補償因傷而受損的功能
Diagnosis, treatment or monitoring
of an injury, or compensation for
an injury



維持或延續生命
Supporting or sustaining life



檢驗、替補、調節或維持
身體結構器官或生理過程
Investigation, replacement,
modification or support of body
structure or function



控制受孕，包括避孕
Control of conception including
contraception



對人體衍生樣本進行體外檢驗，
以提供資料作醫學用途
Providing information for medical purposes
by means of in vitro examination of specimens
derived from the human body



專用於消毒醫療儀器
Specific for medical device disinfection

「醫療儀器」是如何分級的？

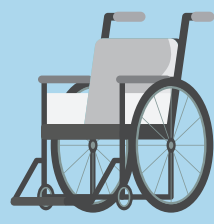



How are "Medical Devices" classified?

醫療儀器可分兩種類型：一般醫療儀器和體外診斷醫療儀器。

There are two types of "Medical Devices":

General Medical Devices and In Vitro Diagnostic Medical Devices.

一般醫療儀器 General Medical Devices

級別 CLASS	I	II	III	IV
例子 EXAMPLE	 輪椅 Wheelchair	 電子體溫計 Electronic thermometer	 電腦斷層 掃描儀 Computerised Tomography Scanner	 心臟 起搏器 Pacemaker
	低 LOW	中-低 LOW-MODERATE	中-高 MODERATE-HIGH	高 HIGH

級別 CLASS	A	B	C	D
例子 EXAMPLE	 尿杯 Plain urine cup	 驗孕產品 Pregnancy self test kit	 家用 血糖機 Home use blood glucose meter	 愛滋病病毒 的測試用品 HIV test kit

體外診斷醫療儀器 In Vitro Diagnostic Medical Devices

更多資訊 For more information:



醫療儀器科
Medical Device Division
www.mdd.gov.hk



衛生署
Department of Health