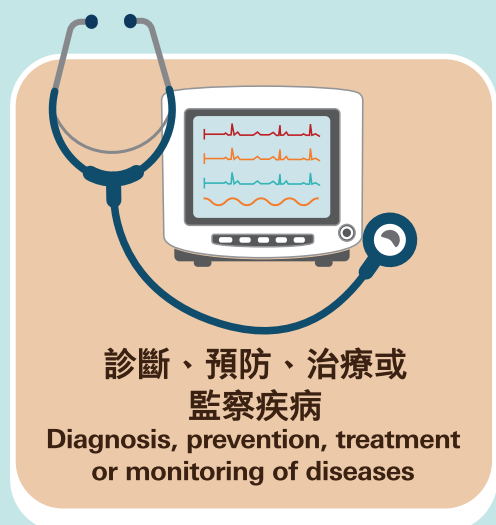# 醫療器械
MEDICAL DEVICES

醫療器械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

專用於消毒醫療器械
Specific for medical device disinfection

「醫療器械」是如何分級的？
How are "Medical Devices" classified?

醫療器械可分兩種類型：**一般醫療器械**和**體外診斷醫療器械**。
There are two types of "Medical Devices": **General Medical Devices** and **In Vitro Diagnostic Medical Devices**.

一般醫療器械 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

體外診斷醫療器械 In Vitro Diagnostic Medical Devices