立法會CB(4)831/18-19(01)號文件
LC Paper No. CB(4)831/18-19(01)

Regulatory Framework of Medical Devices in Other Jurisdictions
其他司法管轄區的醫療儀器監管框架

Food and Health Bureau
Department of Health
食物及衞生局
衞生署

2 May 2019
2019年5月2日

醫療儀器的定義
Definition of Medical Devices

Definition of Medical Devices (HK)
醫療儀器的定義 (香港)

Any instrument, apparatus, implement, machine, appliance, implant, reagent for in-vitro use , software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for any one or more of the specific medical purpose(s) of:-
製造商擬用於人體作以下一項或多項特定醫療用途的任何器材、設備、工具、機器、器具、植入物、體外試劑或校準器、軟件、物料或其他類似或有關物品(無論是單獨或以組合形式使用)：

- diagnosis, prevention, monitoring, treatment or alleviation of disease; or
  診斷、預防、監察、治療或減輕疾病；或
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury; or
  診斷、監察、治療、減輕傷勢或為補償因傷而受損的功能；或
- investigation, replacement, **modification, or support of the anatomy or a physiological process**; or
  檢驗、替補、**調節或維持身體結構或生理過程**；或
- supporting or sustaining life; or
  維持或延續生命；或
- control of conception; or
  控制受孕；或
- disinfection of medical devices; or
  消毒醫療儀器；或
- providing information by means of in vitro examination of specimens derived from the human body
  為從人體抽取的樣本進行體外檢驗或診斷，以提供資料作醫學用途；

AND
does not achieve its primary intended action in or on a human body by pharmacological, immunological or metabolic means, though its intended function may be assisted in by such means
及
而該等儀器並非透過藥物、免疫或新陳代謝的途徑在人體內或人體上達至主要的原擬作用，但可通過這些途徑助其發揮原擬功能。

Definition of Medical Devices (Australia)
醫療儀器的定義 (澳洲)

A medical device is any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;
(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;
(iii) investigation, replacement or **modification of the anatomy or of a physiological process**;
(iv) control of conception;

and that does not achieve its principal intended action in or on the human body by pharmacological,
immunological or metabolic means, but that may be assisted in its function by such means.

Definition of Medical Devices (Canada)
醫療儀器的定義 (加拿大)

Device means an instrument, apparatus, contrivance or other similar article, or an in vitro reagent, including a component, part or accessory of any of them, that is manufactured, sold or represented for use in

a) diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals,
b) restoring, **modifying or correcting the body structure of human beings** or animals or the functioning of any part of the bodies of human beings or animals,
c) diagnosing pregnancy in human beings or animals,
d) caring for human beings or animals during pregnancy or at or after the birth of the offspring, including caring for the offspring, or
e) preventing conception in human beings or animals;

however, it does not include such an instrument, apparatus, contrivance or article, or a component, part or accessory of any of them, that does any of the actions referred to in paragraphs (a) to (e) solely by pharmacological, immunological or metabolic means or solely by chemical means in or on the body of a human being or animal.

Medical device means a device within the meaning of the Act, but does not include any device that is intended for use in relation to animals.

Definition of Medical Devices (EU)
醫療儀器的定義 (歐盟)

Medical device means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or **modification of the anatomy or of a physiological or pathological process or state**,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of medical devices.

Definition of Medical Devices (Japan)
醫療儀器的定義 (日本)

The term "medical device" as used in this Act refers to appliances or instruments, etc. which are intended for use in the diagnosis, treatment or prevention of disease in humans or animals, or intended to **affect the structure or functioning of the bodies of humans** or animals (excluding regenerative medicine products), and which are specified by Cabinet Order.

The term "in-vitro diagnostic" as used in this Act refers to pharmaceuticals intended exclusively for use in the diagnosis of diseases, which are not directly used in the bodies of humans or animals.

Definition of Medical Devices (China)
醫療儀器的定義 (中國)

醫療器械，是指直接或者間接用於人體的儀器、設備、器具、體外診斷試劑及校準物、材料以及其他類似或者相關的物品，包括所需要的電腦軟體；其效用主要通過物理等方式獲得，不是通過藥理學、免疫學或者代謝的方式獲得，或者雖然有這些方式參與但是只起輔助作用；其目的是：

（一）疾病的診斷、預防、監護、治療或者緩解；

（二）損傷的診斷、監護、治療、緩解或者功能補償；

（三）**生理結構或者生理過程的檢驗、替代、調節或者支持**；

（四）生命的支持或者維持；

（五）妊娠控制；

（六）通過對來自人體的樣本進行檢查，為醫療或者診斷目的提供資訊。

Definition of Medical Devices (South Korea)
醫療儀器的定義 (南韓)

"Medical device", as referred to in this Act, shall mean any instrument/machine/device/material or other similar product, used alone or in combination, for human beings or animals, as specified in any of the following Subparagraph: provided that drugs and quasi-drugs, as defined in the Pharmaceutical Affairs Act, and prosthetic limbs/aids among the assistive devices for persons with disabilities, as defined in the Act on Welfare of Persons with Disabilities Article 65, are excluded here from:

1. A product used for the purpose of diagnosis/cure/alleviation/treatment or prevention of disease;
2. A product used for the purpose of diagnosis/cure/alleviation or supplement of injury or impairment;
3. A product used for the purpose of test/replacement or **modification of anatomy or physiologic function**; or
4. A product used for the purpose of contraception.

Definition of Medical Devices (USA)
醫療儀器的定義 (美國)

Device means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is-

1. recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
2. 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
3. intended to **affect the structure or any function of the body of man** or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of mart or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Medical Devices and “Beauty Devices”
醫療儀器 與「美容儀器」

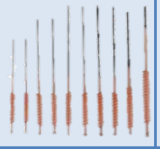
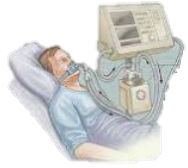
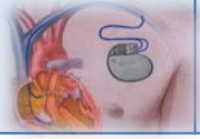
- Difficulties in differentiating Medical Devices and “Beauty Devices”

  區分醫療儀器和「美容儀器」的困難

By Energy Output Level 以輸出能量作區分	By Intended Purposes 以原擬用途作區分	By Intended Users 以原擬使用者作區分
• Energy output level is not used to define medical devices internationally 能量輸出水平並非國際間定義醫療儀器的準則 • For devices adopting same technology, there can be overlap in the range of energy output or the parameter may be similar 就同一技術類型的儀器而言，能量數值可能有重疊或相近的情況	• Medical devices are not limited to treating diseases 醫療儀器不限於只用作治療疾病的儀器 • Whether treatments based on medical principles to achieve cosmetic effects should be regarded as cosmetic procedures is controversial 基於醫學原理達至美容效果的療程是否只應被視作美容程序具爭議性	• Healthcare professionals are not necessarily the only users of medical devices. 醫療儀器並非只是原擬給醫療專業人員使用 • Cannot conclude that a device intended for use by beauty practitioners is not a medical device 不能因儀器原擬由美容從業者使用，便否定該儀器屬醫療儀器

Classification of Medical Devices
醫療儀器的分級

Examples on Classification of Medical Devices
醫療儀器分級的例子

Class 級別	Risk 風險級別	Examples 例子			
I	Low 低	Tongue depressor 壓舌板 	Bandage 繃帶 	Walking aid 助行器 	
II	Medium-Low 中-低	Acupuncture needle 針灸針 	Corrective contact lens 矯視性隱形眼鏡 	Blood pressure monitor 血壓計 	ESWT device 體外衝擊波儀器 
III	Medium-High 中-高	AED 體外除顫器 	Ventilator 肺部呼吸器 	HIFU 高强度聚焦超聲波儀器 	
IV	High 高	Artificial heart valve 人造心瓣 	Implantable pacemaker 植入式心臟起搏器 	Dermal filler 皮膚填充劑 	Breast implant 乳房植入物 

用於美容程序的醫療儀器(以上紅色字例子)只佔醫療儀器的一小部分。
Medical devices used in cosmetic procedures (examples in red) only constitute a small proportion of medical devices.

監管框架
Regulatory Framework

International Medical Device Regulators Forum
國際醫療器械監管機構論壇

- Formed in 2011, the IMDRF is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force (GHTF), and to accelerate international medical device regulatory harmonization and convergence.

  國際醫療器械監管機構論壇（IMDRF）於2011年成立，由來自世界各地的醫療器械監管機構自願組成，在全球協調醫療儀器規管專責小組（GHTF）的基礎上開展工作，並加速國際醫療器械監管協調和融合。

Common Framework for Medical Device Regulations
規管醫療儀器的一般架構

STAGE 階段	PRE-MARKET 推出市面前		POST-MARKET 推出市面後
CONTROL/MONITOR 管制/監察	DEVICE 儀器	SALE 銷售	AFTER-SALE/USE 售後/使用
PERSON 人員	MANUFACTURER 製造商	TRADER 貿易商	TRADER/USER 貿易商/使用者
Items or activities regulated 受管制項目或活動	Device attributes 儀器特徵 • Safety and performance 安全及性能	Establishment registration 機構註冊 • List of products available or in use 醫療儀器清單 • Requires trader to fulfill after-sale obligations 貿易商須履行售後責任	Surveillance 監察 • After-sale obligations 售後責任 • Monitoring of device's clinical performance 監察儀器的臨牀性能 • Problem identification and alerts 問題識別及警報
	Manufacturing 製造 • Quality systems 品質管理系統		
	Labeling 標籤 • Accurate description of product 準確的產品描述 • Instructions for use 使用説明	Advertising 廣告 • Prohibits misleading or fraudulent advertisement 禁止誤導性或虛假的宣傳廣告	

Device Registration Process in Other Jurisdictions
其他司法管轄區的儀器註冊程序

- Common application procedure

  一般申請程序

- Classify the device 為儀器分級
- Select the appropriate submission route 選擇合適的申請途徑
- Prepare necessary documents and submit application 準備文件及遞交申請
- Communicate with regulatory authority and submit supplementary information (if necessary) 與主管當局溝通及遞交補充資料 (如需要)
- Application approved. Obtain license/certificate 申請批准，獲取證書

Application Documents
申請文件

- Submission folder usually includes

  「申請資料夾」通常包括

  - Particulars of Manufacturer (e.g. quality management system certificate)

    製造商資料 (如品質管理系統證書)

  - Particulars of Authorized Representative (e.g. BR certificate, documented procedures)

    授權代表資料 (如商業登記證、書面程序)

  - Particulars of the Device (e.g. Recalls/adverse incidents, labeling, test reports, clinical/performance evaluations)

    儀器詳細資料 (如回收/醫療事故、標籤、測試報告、臨床/性能評估)

  - Marketing Approvals and Essential Principles (e.g. Marketing approvals from GHTF founding members)

    銷售核准及基本原則 (如GHTF 創始成員國的醫療儀器銷售核准證書)

Thank You

謝謝