

與美容業相關的規管和支援措施
Regulatory and Support measures relevant to
the Beauty Industry

立法會衛生事務委員會及工商事務委員會
美容業儀器規管和發展事宜聯合小組委員會

Joint Subcommittee on Issues Relating to the Regulation of Devices
and Development of Beauty Industry

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規管醫療儀器
Regulation of Medical Devices

醫療儀器之定義

Definition of Medical Devices

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)：

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:-

- 診斷、預防、監察、治療或減輕疾病；或
diagnosis, prevention, monitoring, treatment or alleviation of disease;
- 診斷、監察、治療、減輕傷勢或為補償因傷而受損的功能；或
diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- 檢驗、替補、調節或維持身體結構或生理過程；或
investigation, replacement, modification, or support of the anatomy or a physiological process;
- 維持或延續生命；或
supporting or sustaining life;
- 控制受孕；或
control of conception;
- 消毒醫療儀器；或
disinfection of medical devices;
- 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；
providing information by means of in vitro examination of specimens derived from the human body



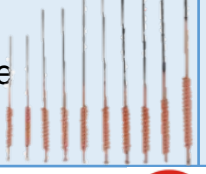



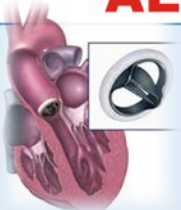

及
而該等儀器並非透過藥物、免疫或新陳代謝的途徑在人體內或人體上達至主要的原擬作用，但可通過這些途徑助其發揮原擬功能。

AND

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

規管醫療儀器

Regulation of Medical Devices

一般醫療儀器 General Medical Device			
級別 Class	風險級別 Level of Risk	例子 Examples	
I	低 Low	壓舌板 Tongue depressor 	繃帶 Bandage 
II	中-低 Medium-Low	針灸針 Acupuncture needle 	矯視性隱形眼鏡 Corrective contact lens 
III	中-高 Medium-High	體外除顫器 External defibrillator 	肺部呼吸器 Lung ventilator 
IV	高 High	人造心瓣 Heart valve 	植入式心臟起搏器 Implantable cardiac pacemaker 

體外衝擊波儀器
ESWT device

高強度聚焦
超聲波儀器
HIFU device

“美容儀器”(以上紅色例子)只佔醫療儀器的一小部分。

“Beauty devices” (the examples above in red) form just a small proportion of medical devices.

作美容用途的醫療儀器

Medical Devices for Beauty Purpose

- 一些作美容用途的儀器符合醫療儀器定義中有關調節或維持身體結構或生理過程的用途。

Certain medical devices for beauty purpose meet the medical device definition about the modification, or support of the anatomy or a physiological process.

- 雖然使用這些儀器的目的是改善外觀，然而其效用是透過醫學原理在人體組織和細胞層面產生作用所達至。

Though the purpose of using those devices is to enhance physical appearance, they bring about effect on human tissues and cells through the application of medical principles.

區分醫療儀器和「美容儀器」的困難

Difficulties in differentiating "Beauty Devices" from Medical Devices

以輸出能量作區分 By Energy Output Level	以原擬用途作區分 By Intended Purposes	以原擬使用者作區分 By Intended Users
<ul style="list-style-type: none">• 能量輸出水平並非國際間定義醫療儀器的準則 Energy output level is not a criteria for defining medical device internationally• 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 Energy output range of devices used for both applications adopting the same technology may be overlapping or similar	<ul style="list-style-type: none">• 醫療儀器不限於只用作治療疾病的儀器 Medical devices are not only intended for treating diseases• 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 It is controversial whether treatments based on medical principles to achieve a cosmetic effect should be considered as cosmetic procedures	<ul style="list-style-type: none">• 醫療儀器並非只是原擬給醫療專業人員使用 Healthcare professionals are not necessarily the only users of medical devices• 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 It cannot be concluded that a device is not a medical device if it is intended for use by beauty practitioners

過渡性「美容儀器」的表列制度

Transitional “Listing System” for “Beauty Devices”

- 實施過渡性「表列制度」，讓未符合醫療儀器註冊規定的「美容儀器」表列。
A transitional “listing mechanism” would be established for “beauty devices” which could not fulfil the registration requirements for medical device.
- 政府在為期五年的過渡期內接受表列儀器申請。符合表列要求並經衛生署表列及或/續期的醫療儀器的有效期為五年。為期五年的過渡期後，政府將不會接受新的醫療儀器表列申請。
Within the five-year transitional window, Government accepts applications for listing. Devices that meet the listing requirement may qualify for a permit to be granted and/or renewed once every five years. Beyond the five-year transitional window, Government will not allow new applications for devices to be listed.
- 已在五年過渡期內表列的儀器，則仍可向衛生署申請續期。
Devices that have been listed within the five-year transitional window may still be subject to renewal of the listing status.
- 儀器的本港貿易商須先向衛生署註冊成為儀器的授權代表，方可向該署提出表列申請，與申請註冊儀器相同。
As with registrable medical devices, a local trader of the concerned device must register with the DH as the authorised representative before filing the listing application to the DH
- 政府相信這項過渡安排，可讓業界逐漸過渡至法定註冊制度並熟習這個制度，長遠而言達至提升香港「美容儀器」的標準。
The Government believe that the transitional arrangement would allow the industry to migrate to and familiarise with the statutory registration regime, with a view to raising the standard of “beauty devices” in Hong Kong in the long run.

支援香港中小型企業（包括美容業）的發展

Funding support for the development of small and medium enterprises in Hong Kong including those in the beauty industry

- 「工商機構支援基金」資助非分配利潤組織推行項目以提升香港整體或個別行業的競爭力
The Trade and Industrial Organisation Support Fund provides financial support to non-profit distributing organisations to implement projects which aim at enhancing the competitiveness of Hong Kong enterprises in general or in specific sectors
- 「發展品牌、升級轉型及拓展內銷市場的專項基金」、「中小企業市場推廣基金」、「中小企業信貸保證計劃」及「中小企融資擔保計劃」下的「特別優惠措施」為香港企業在拓展出口市場、融資及提升整體競爭力等方面提供支援
The Dedicated Fund on Branding, Upgrading and Domestic Sales, the SME Export Marketing Fund, the SME Loan Guarantee Scheme, and the special concessionary measures' under the SME Financing Guarantee Scheme provide support for Hong Kong enterprises in exploring export markets, obtaining finance and enhancing their overall competitiveness

在資歷架構下美容業的發展

Development of Qualifications Framework for the beauty industry

■美容及美髮業培訓諮詢委員會（諮委會）

The Beauty and Hairdressing Industry Training Advisory Committee (ITAC)

- 於2006年成立美容業諮委會，並於2015年與美髮業諮委會合併
set up the Beauty ITAC in 2006, and merged with the Hairdressing ITAC in 2015
- 由僱主、僱員、商會、專業團體及工會代表組成
comprise representatives of employers, employees, trade associations, professional bodies and trade unions
- 協助行業推行資歷架構，並就行業的培訓需求及人力發展交換意見
assist the industries to implement the Qualifications Framework and to exchange views on the training needs and manpower development of the industries

在資歷架構下美容業的發展

Development of Qualifications Framework for the beauty industry

■ 《能力標準說明》 Specification of Competency Standards (SCS)

- 由美容及美髮業諮委會制訂，列明從業員所需具備的技能、知識和需達到的成效標準
developed by the Beauty and Hairdressing ITAC to set out the skills, knowledge and competency standards required of the practitioners to perform various job effectively
- 至今已制定了239個與美容業相關的能力單元
developed 239 beauty-related Units of Competency
- 分佈於九個職能範疇（即化妝、美甲及手足護理、美容保健、美容護理、美體護理、美容教育及培訓、顧客服務及溝通、市場推廣及銷售；以及營運管理）
distributed in nine functional areas (namely Make-up; Nail, Hand and Foot Care; Health Care; Beauty Care; Body Care; Beauty Education and Training; Customer Services and Communication; Marketing and Sales; and Operation Management)

在資歷架構下美容業的發展

Development of Qualifications Framework for the beauty industry

- 美容業有超過250個獲資歷架構認可的課程 (屬於資歷架構第一級至第五級不等)
More than 250 learning programmes in the beauty industry (ranging from QF levels 1 – 5) are recognised under Qualifications Framework
- 當中約100個課程為《能力標準說明》為本課程
Among these learning programmes, about 100 of them are Specification of Competency Standards (SCS)-based.

在資歷架構下美容業的發展

Development of Qualifications Framework for the beauty industry

■ 美容業「過往資歷認可」機制

Recognition of Prior Learning (RPL) mechanism for the beauty industry

- 於2014年推行，確認從業員在工作崗位上積累的技能、知識和相關經驗
launched in 2014 for formal recognition of the skills, knowledge and relevant experience acquired by practitioners in the workplace
- 發展了56個美容業的「過往資歷認可」資歷（涵蓋美容業九個職能範疇，屬於資歷架構第一級至第四級不等）
has developed 56 RPL qualifications covering the nine functional areas for the beauty industry, ranging from QF levels 1 to 4
- 至今已處理了超過1 800項來自美容業的從業員提出在「過往資歷認可」機制下評估其資歷的申請
more than 1 800 applications from practitioners in the beauty industry seeking assessment of their qualifications under the RPL mechanism were processed

僱員再培訓局為美容業提供的培訓課程

Training Courses Organised by the Employees Retraining Board (ERB) for the Beauty Sector

- 1992年成立的法定組織，提供以市場為導向和就業為本的培訓課程及服務，以提升本地勞動力的就業競爭力

Statutory body established in 1992, providing market-driven and employment-oriented **training courses and services** to improve **employability** of local workers

- 服務對象：15歲或以上、具副學位或以下學歷程度人士

Service target: local residents aged 15 or above with education attainment at sub-degree level or below

- 透過約**80**間培訓機構的約**400**間培訓中心，提供約**700**項涵蓋**28**個行業（包括「美容」及「美髮」）的課程；2019-20年度將預留14萬個培訓名額

Offers around **700** courses straddling **28** industries (including “beauty therapy” and “hairdressing”) through the network of about **400** training centres of around **80** training bodies; **140 000** training places will be reserved in 2019-20



僱員再培訓局為美容業提供的培訓課程

Training Courses Organised by the Employees Retraining Board (ERB) for the Beauty Sector

■ 現有53項「美容」或「美髮」行業的課程

53 training courses currently under “beauty therapy” or “hairdressing” industries

- 7項全日制就業掛鈎課程
7 full-time placement-tied courses; and
- 46項兼讀制「新技能提升計劃」課程
46 part-time “Skills Upgrading Scheme Plus” courses

■ 於2017-18年度，共**7 210**學員人次完成美容及美髮業課程

A total of 7 210 trainees completed beauty therapy and hairdressing courses in 2017-18



僱員再培訓局為美容業提供的培訓課程

Training Courses Organised by the Employees Retraining Board (ERB) for the Beauty Sector

- 諮詢19個行業諮詢網絡（包括美容及美髮業），開辦相應培訓課程
To develop related training courses in consultation with its 19 Industry Consultative Network (beauty therapy and hairdressing industry included)
- 可因應個別美容業僱主或行業組織的建議（及提供的空缺），開辦「度身訂造課程」
To develop “Tailor-made Courses” upon suggestions (with provision of vacancies) from individual employers or business associations of the beauty industry

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-End-