1st February 2017

<u>Proposed Regulatory Framework for Medical Devices</u> <u>Views submitted by the Hong Kong Association of Cosmetic Surgery</u>

The Hong Kong Association of Cosmetic Surgery is a professional organization comprising of most of the plastic surgeons practicing cosmetic surgery in Hong Kong.

The Association welcomes the proposed regulatory framework and strongly supports the government to introduce measures to regulate medical devices for cosmetic purposes. The regulation is long overdue since 2004 when only a Voluntary Medical Device Administrative Control System was established.

We have the opinion that:

- 1) A lot of the equipment used for cosmetic purposes are high energy based medical devices (e.g. Laser Class 3B and above, Intense pulsed light (IPL), High intensity focus ultrasound (HIFU), Radiofrequency devices, Cryolipolysis, Microwave therapy etc.). Inappropriate use of these devices without proper medical training and medical supervision will often result in serious permanent complications (skin blister, skin burn, hyperpigmentation, hypopigmentation, skin burn, numbness, nerve injury, eye injury like cataract, corneal damages)
- 2) Robotic Hair Restoration (Hair Transplantation) involves the use of systemic anaesthesia and the widespread infusion of local anaesthetic and other medications into the scalp. Multiple puncture wounds and deep needling of the scalp are done. Hence hair transplantation should be classified as a medical procedure/cosmetic surgery by its nature and should not be included into the scope of cosmetic procedures.
- 3) As technology advances rapidly, there will be new cosmetic devices being deployed into the field with time. It is essential that timely re-examination and updating of the devices classification performed by an authorized committee regularly in a scheduled time frame.

Thank you fro your attention.

Yours sincerely,

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