

- Beauty plano lenses (俗稱大眼仔), not classified as medical device (MD) under the current definition (GN-00 Clause 2.37) by Hong Kong Medical Device Control Office (MDCO) (whereas contact lenses are regarded as Class II MD under GN-01), are normally worn by the public at the same manner as ordinary contact lenses. As such, beauty plano lenses pose the same degree of safety concerns as ordinary contact lenses.
- Due to the use of pigments in beauty lenses, oxygen permeability is hindered if this is not taken in account during the design of the lens. Hence beauty plano lens could possibly be even less safe than ordinary contact lenses as our eyes need adequate oxygen to keep healthy.
- Safety and quality of certain beauty plano lenses (as well as ordinary contact lenses) are in question because they could either be manufactured in other countries with the lack of Good Manufacturing Practice (GMP) or in countries where beauty lenses are not regulated as medical devices. Imported beauty plano lenses could pose serious hazards to the public in HK if they are not locally controlled as medical devices like ordinary contact lenses. For example, in some countries, the use of pigments in beauty contact lens is not controlled by the government.
- Compliance of beauty contact lenses wearers were also found to be poor with research showing that beauty wearers tend to wear a daily disposable beauty lens for 2.9 days (TNS beauty lens usage frequency, 2014)
- Beauty plano lenses is not classified as MD under the current GN-00 by MDCO. Therefore, we strongly recommend that a separate appendix should be added to the future legislative document so that they can be regulated in the same manner as ordinary contact lenses (Class II MD).

SELLING OF CONTACT LENSES (as Class II Medical Device)

- Selling of contact lenses without proper education from eye care professionals can pose a big threat to the public.
- Eye care professional are obligated to ensure the quality, suitability of the contact lenses to the consumers. Eye care professional are the most appropriate professional to safeguard public eye health or else public has no way to learn about the proper lens wearing and handling procedures (i.e. insertion and removal of contact lenses, disinfection of contact lenses which also involves the use of contact lens solution (Classified as Class III MD))
- Contact lenses should only be sold by MD licence holders, MD registered distributors, any institutions or business operations (either online or offline) under the direct physical supervision of a qualified eye care professional.

IMPORTATION OF CONTACT LENSES (as Class II Medical Device)

- Importation of medical devices (including Class II MD contact lenses) should be effectively controlled. Importers of medical devices should acquire an import licence issued by HK MDCO or other government department for each consignment to be shipped into HK. This is to avoid any medical devices without approved quality (due to counterfeits, unknown sources, improper storage during transportation, etc) from being imported into HK, so as to safeguard the health of the public.
- As in the case of Singapore, the importers must obtain the relevant certifications and licence from the Authority. This is to ensure the conformity of the MD to the required standards of safety, performance and quality.
- Counterfeit beauty contact lenses had been found in Singapore which raise the public health and safety concern. Laboratory analysis by the authority has confirmed that these counterfeit beauty contact lenses were unsafe, of poor quality and deficient in many aspects. This case clearly demonstrated that it is important to control the importation of contact lenses.

http://www.hsa.gov.sg/content/hsa/en/News_Events/Press_Releases/2011/hsa_alerts_public3.htm
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