Documents Essential to Medical Device Listing Application under MDACS

The Medical Device Administrative Control System (MDACS) is in place to ensure that medical devices supplied in Hong Kong meet the requirements on safety, quality and performance. To apply for listing under the MDACS, a medical device must be proven to have met the requirements under the Essential Principles of Safety and Performance of Medical Devices that are adopted internationally.

The Local Responsible Person (LRP) is advised to include, **at a minimum**, the following documents in the application submission for listing of a medical device under MDACS via the Medical Device Information System (MDIS). The LRP must ensure that the application form and all the associated submissions are **properly prepared before** they are submitted. Furthermore, the LRP has the obligation to submit further information (including original or certified true copies of documents) or further labelling samples related to the application if this is requested by the Medical Device Division. Failure of the LRP to provide information requested by the Medical Device Division **may result in the listing application being closed**.

Essential Document Applicable to Manufacturer and Manufacturing Site(s)		
1.	Manufacturer	**ISO 13485 certificate;** (or medical device production licence (「醫療器械生產許可」) if the medical device is registered with the National Medical Products Administration only.)
2.	Manufacturing site(s)	**ISO 13485 certificate;** (or medical device production licence (「醫療器械生產許可」) if the medical device is registered with National Medical Products Administration only.)
3.	Manufacturer and Medical Device	**Marketing approval** documents from Chinese Mainland, Australia, Canada, the European Union (EU), Japan, Singapore, South Korea or the USA; or **MDACS Conformity Assessment Certificate**

Essential Document Applicable to LRP	
1.	Hong Kong **Business Registration Certificate**
2.	**Manufacturer's letter** for designating an LRP
3.	**Documented procedures** of LRP (for new LRP or change(s) in documented procedures)
4.	**Other local licence(s)** such as the Wholesale Dealer Licence of Pharmaceutical Products under the Pharmacy and Poisons Ordinance (Cap. 138), Irradiating Apparatus Licence under the Radiation Ordinance (Cap. 303)

Essential Document Applicable to Medical Device	
1.	Summary of all **recalls, reportable adverse events, banning in other countries** related to the medical device
2.	Device **labelling sample** (including Instructions for Use and package label)
3.	**Special Listing Information** (Contact of LRP shall be a local telephone number)
4.	**Other local licence(s)** such as Irradiating Apparatus Licence under Cap. 303
5.	**Risk analysis** report or summary
6.	For General Medical Device: **Clinical evaluation report** or clinical evidence (Duly dated and signed by author(s)) For In Vitro Diagnostic Medical Device: **Performance evaluation report** or clinical evidence (Duly dated and signed by author(s))
7.	**Marketing approval** documents from Chinese Mainland, Australia, Canada, the European Union (EU), Japan, Singapore, South Korea or the USA; or **MDACS Conformity Assessment Certificate**
8.	**Essential Principles Conformity Checklist** (Form MD-CCL or MDIVD-CCL); or Designated documents in lieu and the Essential Principles Declaration of Conformity (Designated documents mean Essential Requirements Checklist or General Safety and Performance Requirements Checklist. Sample of Essential Principles Declaration of Conformity is stipulated in Appendix I of Guidance Notes GN-02 "Guidance Notes for Listing Class II, III & IV Medical Devices" and GN-06 "Guidance Notes for Listing In Vitro Diagnostic (IVD) Medical Devices".)

Note: The above aims to provide useful information on medical device listing application for Local Responsible Person's (LPR's) reference only. The LRP shall always refer to relevant Guidance Notes and Technical References of MDACS for latest requirement(s). For enquiries, please contact the Medical Device Division.