

Medical Device Division
Renewal and/or Change Application Form for
Listed Local Manufacturers

To: **Medical Device Division (Fax No: 3157 1286)**
(Attn: Secretary, LMLAB)

Reference No: LMAN_____ Listing No: LM_____

Please complete the following table and return it to Medical Device Division with copies of updated documents, e.g. a valid business registration certificate, Quality Management System (ISO 13485) Certificate (if applicable) and the latest list of medical devices manufactured and to be manufactured by you.

Item	Description	Check the appropriate box, if there is any change/ update	Details <i>(Use separate sheet if necessary)</i>
1(a)	Name of Local Manufacturer (in English)	<input type="checkbox"/>	
1(b)	Name of Local Manufacturer (in Chinese)	<input type="checkbox"/>	
2	Address in HK	<input type="checkbox"/>	
3	Business Registration Certificate (Cert No. _____)	<input type="checkbox"/>	
4	Contact information: - Management Representative's/ Deputy Management Representative's name and position - Telephone - Fax - Email - Mobile no. (after office hours) - Website	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
5	Quality Management System certificate (e.g. ISO13485)	<input type="checkbox"/>	
6	Listed scope of manufacture (this must not exceed the scope of certification stated in the Quality Management System certificate)	<input type="checkbox"/>	
7	List of medical devices manufactured and to be manufactured	<input type="checkbox"/>	

