

Medical Device Division

Renewal and Change Application Form for Listed Importers/Distributors

To: Medical Device Division (Fax No: 3157 1286)
(Attn: Secretary, ILAB/DLAB)

Application(s):	Reference no.:	Listing no.:
<input type="checkbox"/> Change of a Listed Importer	IAN _____	IMP _____
<input type="checkbox"/> Renewal of a Listed Importer		
<input type="checkbox"/> Change of a Listed Distributor	DAN _____	DIS _____
<input type="checkbox"/> Renewal of a Listed Distributor		

Please complete the following table and return it to Medical Device Division with copies of updated documents, e.g., a valid business registration certificate, revised documented procedures (if applicable) and the latest List of medical devices imported and to be imported / distributed and to be distributed.

Item	Description	Check appropriate boxes if there is any change/update	Remarks (Use separate sheet if necessary)
1(a)	Name of Importer/Distributor (in English):	<input type="checkbox"/>	
1(b)	Name of Importer/Distributor (in Chinese):	<input type="checkbox"/>	
2	Company address in Hong Kong:	<input type="checkbox"/>	
3	Business Registration Certificate (Certificate no. _____) <i>(For Body Corporate or Partnership applicants)</i>	<input type="checkbox"/>	

4	Contact Information		
	- Contact person's name and position	<input type="checkbox"/>	
	- Telephone:	<input type="checkbox"/>	
	- Fax:	<input type="checkbox"/>	
	- Email:	<input type="checkbox"/>	
	- Mobile phone no. (non-office hours)	<input type="checkbox"/>	
	- Company website	<input type="checkbox"/>	
5	Quality Management System certificate(s) (e.g. ISO 9001, ISO 13485)	<input type="checkbox"/>	
6	List of medical devices imported and to be imported / distributed and to be distributed	<input type="checkbox"/>	
7	Documented procedures		
	- (For Importers) Ensuring the standard of medical devices imported	<input type="checkbox"/>	
	- Keeping of supply records	<input type="checkbox"/>	
	- Handling, storage and delivery of medical devices	<input type="checkbox"/>	
	- Management of safety alerts, field safety notices and recalls	<input type="checkbox"/>	

	- Managing reportable adverse events in Hong Kong	<input type="checkbox"/>	
	- Complaints handling	<input type="checkbox"/>	
	- Tracking of specific medical devices	<input type="checkbox"/>	
	- Maintenance and services arrangements	<input type="checkbox"/>	
8	Others (please specify):	<input type="checkbox"/>	

(Signature)

(Name)

(Position)

(Date)

(Company chop)
