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.: |
|  | Change of a Listed Importer | IAN | IMP |
|  | Renewal of a Listed Importer |
|  | Change of a Listed Distributor | DAN | DIS |
|  | Renewal of a Listed Distributor |

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| 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): | | |  |  | |
| 1(b) | | Name of Importer/Distributor (in Chinese): | | |  |  | |
| 2 | | Company address in Hong Kong: | | |  |  | |
| 3 | | Business Registration Certificate (Certificate no.      )  *(For Body Corporate or Partnership applicants)* | | |  |  | |
| 4 | | Contact Information | | | | | |
|  | | * Contact person’s name and position | | |  |  | |
|  | | * Telephone: | | |  |  | |
|  | | * Fax: | | |  |  | |
|  | | * Email: | | |  |  | |
|  | | * Mobile phone no. (non-office hours) | | |  |  | |
|  | | * Company website | | |  |  | |
| 5 | | Quality Management System certificate(s) (e.g. ISO 9001, ISO 13485) | | |  |  | |
| 6 | | List of medical devices imported and to be imported / distributed and to be distributed | | |  |  | |
| 7 | | Documented procedures | | | | | |
|  | | * (For Importers) Ensuring the standard of medical devices imported | | |  |  | |
|  | | * Keeping of supply records | | |  |  | |
|  | | * Handling, storage and delivery of medical devices | | |  |  | |
|  | | * Management of safety alerts, field safety notices and recalls | | |  |  | |
|  | | * Managing reportable adverse events in Hong Kong | | |  |  | |
|  | | * Complaints handling | | |  |  | |
|  | | * Tracking of specific medical devices | | |  |  | |
|  | | * Maintenance and services arrangements | | |  |  | |
| 8 | | Others (please specify): | | |  |  | |
|  | (Signature) | | |  |  | |  |
|  |  | | (Name) |  |  | |  |
|  |  | | (Position) |  |  | |  |
|  |  | | (Date) |  | (Company chop) | |  |
|  |  | |  |  |  | |  |