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 |

|  |
| --- |
| 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) |  |
|  |  |  |  |  |  |