

Medical Device Control Office
Renewal Form for Listed Medical Devices

To: **Medical Device Control Office**

<i>For official use only</i>
Date Received (dd/mm/yyyy): _____
Application No.: _____

Particulars of Application

1	HKMD No.	
	Make	
	Model	
	Company Name	
	Contact Person	
	Telephone	
	E-mail	
2	A copy of valid Business Registration Certificate (number: _____) is enclosed.	
3	<u>There are active recalls, field safety corrective actions or adverse incidents (local and worldwide)</u> <input type="checkbox"/> No <input type="checkbox"/> Yes. Details are provided in separate sheets.	
4	<u>There is change to the listing details since last approval</u> <input type="checkbox"/> No <input type="checkbox"/> Yes (Please go to 4(i))	
	(i)	<u>Change application of the devices is submitted to MDCO</u> <input type="checkbox"/> Yes <input type="checkbox"/> No. We will submit change application within 10 calendar days.

Declaration

We acknowledge that the listing details of this renewal application would be the same as the last approved version. Approval of this renewal application does not imply the approval of any change application in progress.

We confirm that:

- a. The applicant remains designated as Local Responsible Person by the manufacturer;
- b. The applicant remains aware and complies with all device listing conditions (e.g. Post market surveillance);
- c. All certifications / licences (e.g. ISO 13485 certificate for manufacturing site and recognized marketing approval) relating to the listed device remain valid and will be submitted to MDCO upon request; and
- d. The information contained in this renewal form is true and correct.

Signature of Applicant:

Name: _____

Position: _____

Date (dd/mm/yyyy): _____

_____ Company Chop