Medical Device Division (MDD)
Department of Health

Medical Device Administrative Control System
Post-Market Surveillance (PMS) Report Form

THIS REPORT SHALL BE SUBMITTED ANNUALLY TO MEDICAL DEVICE DIVISION IN ACCORDANCE WITH LISTING APPROVAL LETTERS

To: Medical Device Division MDD Reference: AN_____

HKMD No.		Date of submission	
Covering period of PMS report*	From: (dd/mm/yy) To: (dd/mm/yy)		
Total pages (including enclosures)			

Part A: Particulars of LRP			
LRP Name		LRP Number	
Name of Contact Person		Email	
Position		Telephone	
Fax		Mobile	

Part B: Particulars of the Medical Devices			
Make/Brand/Model (Product codes)			
Risk Class		AMDNS Code & Term	

Number of the Devices Supplied

Model	Year	Hong Kong	Worldwide	Total

Post-market Events

If there is any post-market event for the devices in the period covered in this report, please
(a) put a tick in appropriate box(es);
(b) complete relevant parts in this form; and
(c) enclose supplementary information if applicable/necessary (e.g. increasing trend in the reporting of complaints / safety issues / adverse events, investigation results for reported complaints, safety alerts / recalls and/or adverse events):

Post-market events	Check the box where applicable	The Part in this form required to be completed	Enclosure

(1) Complaints	☐	Part C	☐
(2) Recalls / Field Safety Notices	☐	Part D	☐
(3) Adverse events	☐	Part E	☐
(4) Regulatory actions from any country	☐	Part F	☐
(5) Post-market surveillance studies	☐	Part G	☐

Part C: Details of Complaints Reported for the Devices					
Model	Year	Hong Kong		Worldwide	
		Number	Rate	Number	Rate
Details and data analysis of reported complaints should be given in the **enclosure**.					

Part D: Details of Recalls / Field Safety Notices for the Devices					
Model	Year	Hong Kong		Worldwide	
		Number	Rate	Number	Rate
ALL preventive/corrective actions for the recalls / field safety notices are satisfactorily completed.				◯ Yes	◯ No
Details and data analysis of all recalls / field safety notices should be provided in the **enclosure**.					

Part E: Details of Adverse Events Reported for the Devices					
Model	Year	Hong Kong		Worldwide	
		Number	Rate	Number	Rate

ALL actions for adverse events are satisfactorily completed.				◯ Yes	◯ No
Details and data analysis of all adverse events should be provided in the **enclosure**.					

Part F: Regulatory Actions Taken by Other Countries			
Type of Regulatory Actions	☐ Device(s) banned	☐ Marketing approval withdrawn	☐ Recalls mandated
	☐ Restrictions imposed	☐ Others (please specify:)	
Countries involved			
Details of all regulatory actions should be provided in the **enclosure.**			

Part G: Post-market Surveillance Studies			
Post-market Surveillance Studies	☐ Laboratory testing	☐ Market surveys on information	☐ Risk analysis
	☐ Clinical trials	☐ Others (please specify:)	
Is there **ANY** unfavorable result from the studies that may affect quality, safety and performance of the devices?		◯ Yes	◯ No
Details of post-market surveillance studies should be provided in the **enclosure.**			

Name: Position:

Signature: Date:

Company chop: