

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				
Manufacturer/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	<input type="checkbox"/>	Part C	<input type="checkbox"/>
(2) Recalls / Field Safety Notices	<input type="checkbox"/>	Part D	<input type="checkbox"/>
(3) Adverse events	<input type="checkbox"/>	Part E	<input type="checkbox"/>
(4) Regulatory actions from any country	<input type="checkbox"/>	Part F	<input type="checkbox"/>
(5) Post-market surveillance studies	<input type="checkbox"/>	Part G	<input type="checkbox"/>

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	<input type="checkbox"/> Device(s) banned	<input type="checkbox"/> Marketing approval withdrawn	<input type="checkbox"/> Recalls mandated
	<input type="checkbox"/> Restrictions imposed	<input type="checkbox"/> 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	<input type="checkbox"/> Laboratory testing	<input type="checkbox"/> Market surveys on information	<input type="checkbox"/> Risk analysis
	<input type="checkbox"/> Clinical trials	<input type="checkbox"/> 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: