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

MDD Reference: AN

To: Medical Device Division

HKMD No.			Dat	te of subm	ission			
Covering period of PMS report*		From: (dd/mm/yy)	To:	(dd/mm/yy)			
Total pages (including enclosures)								
Part A: Particulars of I	.RP							
LRP Name			LRP Number	r				
Name of Contact Perso	on		Email					
Position		Telephone						
Fax			Mobile					
Part B: Particulars of t	ho Modical Dovi	ros						
Make/Brand/Model	ne Medical Devi	Les						
(Product codes)								
Risk Class		AMDNS Cod & Term	de					
Number of the Device	s Supplied	& lellil						
Model		Year	Hong	Worldwide			Total	
			Kong					
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 b	Check the box where		The Part in this form			
		applicable		required	to be complete	ed		
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(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							
Model	Teal	Year Hong Kong Number Rate		Number Rate			
		- rearrise:	riace	ramer	nace		
Data the sent data and also for a sent advanced	-1-1-111		Us a sealest				
Details and data analysis of reported com	ipiaints snoui	d be given in	the enclosu	re.			
Part D: Details of Recalls / Field Safety Notices for the Devices							
Model	Year	Hong		Worldw			
			Kong Rate	Worldw Number	vide Rate		
		Hong					
		Hong					
		Hong					
<u> </u>		Hong					
		Hong					
		Hong					
		Hong					
		Hong					
		Hong					
Model	Year	Hong Number	Rate				
Model ALL preventive/corrective actions for the	Year	Hong Number	Rate				
ALL preventive/corrective actions for the satisfactorily completed.	Year recalls / field	Number safety notice	Rate	Number	Rate		
Model ALL preventive/corrective actions for the	Year recalls / field	Number safety notice	Rate	Number	Rate		
ALL preventive/corrective actions for the satisfactorily completed. Details and data analysis of all recalls / fie	recalls / field	Number safety notice	Rate	Number	Rate		
ALL preventive/corrective actions for the satisfactorily completed.	recalls / field	Number safety notice ices should b	Rate es are e provided i	Number	Rate No		
ALL preventive/corrective actions for the satisfactorily completed. Details and data analysis of all recalls / fie Part E: Details of Adverse Events Reported	recalls / field	Number safety notice	Rate es are e provided i	Yes n the enclosure .	Rate No		
ALL preventive/corrective actions for the satisfactorily completed. Details and data analysis of all recalls / fie Part E: Details of Adverse Events Reported	recalls / field	Number safety notice ices should b	Rate es are e provided i	Yes n the enclosure .	No		
ALL preventive/corrective actions for the satisfactorily completed. Details and data analysis of all recalls / fig. Part E: Details of Adverse Events Reported.	recalls / field	Number safety notice ices should b	Rate es are e provided i	Yes n the enclosure .	No		

Part C

(1) Complaints

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ALL actions for adverse events are satisfactorily completed. Yes								
Details and data ana	lysis of all adverse eve	nts should k	oe provided ir	the enclo	sure.			
			•					
Part F: Regulatory A	ctions Taken by Other	Countries						
Type of Regulatory	☐ Device(s) banned ☐ Marketing approval w			oroval with	drawn 🔲	Recalls manda	ated	
Actions	Restrictions impo	osed 🔲 (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 Laboratory		testing	Market surveys on information			Risk analysis		
Studies	Clinical tria	ls [Others (please specify:)					
Is there ANY unfavorable result from the studies that may affect quality, safety and performance of the devices?								
Details of post-market surveillance studies should be provided in the enclosure.								
Name:			Position:					
Signature:	Date:							
Company chop:								

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