**Medical Device Division (MDD)**

**Department of Health**

**Medical Device Administrative Control System**

**Post-Market Surveillance Report Form for Specified Class II/III/IV Medical Devices\***

**To:** To: Medical Device Division (Fax No: 3157 1286) MDD Reference: AN\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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

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| **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 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 | [ ]  |

\* This report shall be submitted annually to MDD for the medical devices specified in the listing approval letter

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

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| **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**. |

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| **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**. |

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| **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.** |

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| **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.** |

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| Name:       | Position:       |
| Signature:  | Date:       |
| Company chop: |