**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) |  | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **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 | |
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| **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 |
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| **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 |
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| **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.** | | | | | |

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