**Medical device malfunction / infection case report**

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| **1. Management information** |
| 1) Control number | Identification number | 　- | Registration number | - | Known/ unknown |  |
| Report Deadline  |  |  Location of Event  |  |
| 2) Report Category | Classification |  | Type |  | Receipt number of the previous report:( )  |
| 3) Date of Event |  | 4) Date of information obtained |  |
| 5) Report date |  | 6) Next scheduled report date |  |
| 7) Health status of patients |  |
| 8) Medical device malfunction status |  |
| 9) Contact person | Name |  | Company |  |
| Department |  |
| Address |  |
| Tel |  | Fax |  |
| E-mail |  |
| **2. Patient information** |
| 1) Patient's initial |  |  2) Age |  | 3)Gender |  | 4) Weight |  |
| 5) Outcome |  |
| 6) Patient status at the time of malfunction |  |
| 7) Treatment taken |  |
| **3. Medical device information** |
| 1) Product name |  |
| 2) Generic name |  |
| 3) Detailed information of the device |  |
| 4) Approval / certification number, etc. |  |
| 5) Medical device classification |  |
| 6) Usage Status  |  □Initial Use |  Number of times used ( times)or (Period after use months or days  or hours) |
| 7) Current status of medical devices |  (□Disposed □Remains in body □To be retrieved  □Unretrievable ) |
| 8) Name of devices used together |  |
| 9) Remarks |  |
| **4. Investigation results and actions etc.** |
| 1) Investigation results |  |
| 2) Actions taken so far |  |
| 3) Future actions |  |
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Dear Chairman of Pharmaceutical and Medical Device Agency,

 We report the malfunctions and infections case related to medical devices.

 Date :

 Address:

 Name :