**Report on changes on occurrence rate of medical device defects**

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| **1. Management information** |
| 1) Control number | Identification number |  | Registration number |  |  |
| Location of Event | ①Domestic | ② Foreign |  |
| 2) Report Category | Type | ① Initial report | ② Additional report | Receipt number of the previous report: (　　　　　) |  |
| 3) Device Approval /Certification /Notification date |  | 4) Analysis date |  |
| 5) Report date |  | 6) Date designated by the Minister |  |
| 7) Reporting period |  |
| 8) Next report date |  |  |
| 9) Contact person  | Name |  | Company |  |
| Department |  |
| Address |  |
| Tel |  | Fax |  | E-mail |  |
| **2. Medical device information** |
| 1) Product name |  |
| 2) Generic name  |  |
| 3) Details of the device |  |
| 4) Approval/certification number, etc. |  |
| 5) Medical device classification | ① Highly controlled medical device | ② Controlled medical device | ③ General medical device |
| ① Biological medical equipment | ② Specified biological medical device | ③ Other |
| 6) Remarks |  |
| **3. Malfunction information** |
| 1) Title |  |
| 2) Occurrence mechanism |  |
|  |
| 3) Current Occurrence rate |  | 4) Updated Occurrence rate  |  |
| 5) Analysis method |  |
|  |
| 6) Actions taken so far | ① Recall | ② Request for suspension of use | ③ Provide information | ④ Other |
|  |
| 7) Future actions | ① Recall | ② Request for suspension of use | ③ Provide information | ④ Other |
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| **4. List of health hazards** |
| 1) Number | 2) Health hazard status | 3) Outcome | 4) Number of cases | 5) Measures taken |
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 Dear Chairman of Pharmaceutical and Medical Device Agency,

 We report the investigation result related to the medical device.

 Date :

 Address:

 Name :