**Periodic report for designated medical devices**

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| **1. Management information** |
| 1) Control number |  |  |
| 3) Device Approval /Certification /Notification date |  | 4) Analysis date |  |
| 5) Report date |  | 6) Date designated by the Minister |  |
| 7) Reporting period |  |
| 8) 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) Classification |  | ① Highly controlled medical device (Class Ⅳ) | ②Highly controlled medical device (Class III) | ③ Controlled medical device |
|  | ④ General medical device | ⑤ Combination products (pharmaceuticals) | ⑥ Combination products (regenerative medicine products) |
|  | ⑦ Software (Class Ⅳ) | ⑧Software(Class III) | ⑨Software (Class II) |
| ① Biological medical device  | 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 :