**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 :