**Medical device unknown non-serious defect periodic report**

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| **1. Management information** | | | | | | | | | | | | | | | | | |
| 1) Control number | |  | | | | | |  | | | | | | | | | |
| 2) Device Approval /Certification/ Notification date | | |  | | | | | | | 3) Report date | | | | |  | | |
| 4) 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) | | | | | | | (2) Highly 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 | | | |  | | | | | | | | | | | | | |

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| **3. List of malfunction status** | | | | | |
| 1) Number | 2) Malfunction Status | 3) Health hazard status | 4) Outcome | 5) Number of cases | 6) 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 :