**Medical device investigation report**

**on measures taken outside of Japan / on research paper**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1. Management information** | | | | | | | | | | | | | | |
| 1) Control number | Identification number | | | | - | | | | Registration number | | | | - | |
| Report category |  | | | |  | | | | | | | | |
| 2) Report  Category | Classification |  | | | | Type | |  | | Receipt number at the time of the previous report:  　( ) | | | | |
| 3) Date of information obtained | | |  | | | | 4) Report date | | | | |  | | |
| 5) Next scheduled report date | | | |  | | | | | | | | | | |
| 6) Health hazard status of patients, etc. | | | | |  | | | | | | | | | |
| 7) Medical device malfunction status | | | | |  | | | | | | | | | |
| 8) Contact  person | Name |  | | | | | | | Company |  | | | | |
| Department |  | | | | |
| Address |  | | | | | | | | | | | | |
| Tel |  | | | | | | | Fax | |  | | | |
| E-mail |  | | | | | | | | | | | | |
| **2. 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) Remarks | | | | |  | | | | | | | | | |
| **3. Report contents and responses** | | | | | | | | | | | | | | |
| 1) Research report or measure details | | | | | Source of  research report | | | | | | | | |  |
| Country where the measure was taken | | | | | | | | |  |
| Measure category | | | | | | | | |  |
|  | | | | | | | | | | | | | | |
| 2) Actions taken so far | | | | |  | | | | | | | | | |
| 3) Future actions | | | | |  | | | | | | | | | |
|  | | | | | | | | | | | | | | |

Dear Chairman of Pharmaceutical and Medical Device Agency,

We report the investigation result related to the medical device.

Date :

Address:

Name :