**Medical device investigation report**

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

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| **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 |  |
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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 :