Format No.3

Created on YYYY/MM/DD

List of Documents

Applicant:

Device Name:

Name of the document under review:

Name of the test facility:

Test Period:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Category | Sub Category | Document No. | Document Name/Number | Can the original be sent to PMDA?(Yes/No) | Reason (If the original can’t be sent) | Quantity | Sent/Received date |
| Applicant | PMDA |
| Pages | Volume | Sent | Received | Sent | Received |
| A | Record of test plan | 1 | Test plan |  |  |  |  |  |  |  |  |  |  |
| 2 | Test Protocol (Note1) |  |  |  |  |  |  |  |  |  |  |
| 3 | Analysis protocol |  |  |  |  |  |  |  |  |  |  |
| B | Record of test | 1 | Experiment notes, worksheets, charts, checklists, memos with test result, etc. |  |  | □Hand-written record |  |  |  |  |  |  |  |  |
| □Electromagnetic records(direct manual input) |
| □Electromagnetic records (Automatic measurement) |
| □Other records |
| 2 | List of equipment used (Note2) |  |  |  |  |  |  |  |  |  |  |
| C | Record of equipment management /inspection | 1 | Records of daily maintenance (Note3) |  |  |  |  |  |  |  |  |  |  |
| 2 | Calibration certificate (Note4) |  |  |  |  |  |  |
|  |  |  |  |  |  |
| 3 | In-house calibration record (Note4) |  |  |  |  |  |  |
|  |  |  |  |  |  |
| D | Record of test report | 1 | Test report |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |
| 2 | Correction document of test report | 12 |  |  |  |  |  |
| 3 | Test report corrected based on the correction document | 13 |  |  |  |  |  |
| E | Record related to internal checks such as data | 1 |  | 14 |  |  |  |  |  |
| 2 |  | 15 |  |  |  |  |  |
| F | Other records | 1 |  | 16 |  |  |  |  |  |
| 2 |  | 17 |  |  |  |  |  |
| （Remarks） |

(Note1) Please submit what was used when the test was conducted.

(Note2) Please also submit a list of the tester's name, test date, equipment used, sample lot number, etc.

(Note3) Not required if you have a calibration certificate or in-house calibration records.

(Note4) Please submit the record that was valid at the time of the test.