**Vigilance/Recall Search Report**

For

[Device Name]

Manufacturer Name: [Manufacturer name]

Document Number: XXXX

Revision: XXXX

# Approval

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# Revision History

Table 1: History of revision

|  |  |  |
| --- | --- | --- |
| Revision | Date | Change History |
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# Acronyms

|  |  |
| --- | --- |
| AC | Acceptance criteria |
| ANSM | Agence nationale de sécurité du médicament et des produits de santé |
| Bfarm | Bundesinstitut für arzneimittel und medizinprodukte |
| DAEN | Database of adverse event notifications |
| EU | European union |
| FDA | Food and drug administration |
| FSCA | Field safety corrective action |
| MAUDE | Manufacturer and User Facility Device Experience |
| MHRA | Medicines and healthcare products regulatory agency |
| SARA | System for australian recall actions |
| SoA | State of the art |
| S&P | Safety and performance |
| TGA | Therapeutic goods administration |
| TPLC | Total product lifecycle |
| UK | United Kingdom |
| US | United States |

# Objective

The vigilance/recall search report has been carried out according to the protocol [protocol number and revision]. A systematic approach has been applied to collect clinical risks (i.e., device problem, patient problem) reported for [Device Name], hereafter named [device short name], its equivalent device (Objective 3 of safety and performance [S&P]) and similar devices (Objectives 2 of S&P acceptance criteria [AC]).

# Deviation to the protocol

No deviation to the protocol described in **Section 1**.

*All deviations need to be justified for their impact on the results.*

# Search period

The vigilance/recall search report is defined to cover the period from [start date (DD Month YYYY)] to [end date (DD Month YYYY)].

As described in the protocol indicated in **Section 1**, *Include a justification how the period selected is appropriate (copy/paste justification from the protocol)*

# Search method

## Vigilance/recall search database

The following vigilance/recall databases have been selected to collect clinical risks reported on the market for [device short name]/equivalent device and similar devices.

Table 2: Search databases for vigilance/recall

| **Vigilance / Recall database** | **Objective** | **Justification *(copy/paste the justification from the protocol)*** |
| --- | --- | --- |
| **SoA** | **AC** | **S&P** |
| [FDA MAUDE](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm) |  | X | X | “MAUDE” is the database to report the adverse events occurred in US. Though the population involved and the procedure applied may differ as compared to the population and procedure in EU, this bias is not considered significant. [Device short name] and similar devices is/are sold in US, hence the database is deemed relevant to collect applicable clinical risks (device or patient problem) for the S&P and AC objectives. |
| [FDA Medical Device Recalls](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm) |  | X | X | “FDA Medical Device Recalls” is the database to report recalls in US. Though the population involved and the procedure applied may differ as compared to the population and procedure in EU, this bias is not considered significant. [Device short name] and similar devices is/are sold in US, hence the database is deemed relevant to collect applicable clinical risks for the S&P and AC objectives. |
| [FDA TPLC](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm) |  | X |  | TPLC is a database that describes the types and quantity of significant adverse events and recalls reported in US for a specific product code or regulation number. As the database is not specific to the subject device, it is not used to support the S&P objective. However, the database is relevant to give an overview of clinical risks reported in US for devices with the same technology. Though the population involved and the procedure applied may differ as compared to the population and procedure in EU, this bias is not considered significant. |
| [ANSM safety information](https://ansm.sante.fr/informations-de-securite/) |  | X | X | *Database with limited value as the results are only in French.*“ANSM safety information” is one of the EU databases for recalls, field safety notices, and ANSM safety alerts reported in France. [Device short name] and similar devices is/are sold in France, hence the database is deemed relevant to collect applicable clinical risks for the S&P and AC objectives. |
| [Bfarm Field Corrective Actions](https://www.bfarm.de/SiteGlobals/Forms/Suche/EN/Expertensuche_Formular.html?nn=708434&cl2Categories_Format=kundeninfo) |  | X | X | *Database with limited value as the period of search is not sufficiently detailed.*“Bfarm Field Corrective Actions” is one of the EU databases for field safety corrective actions (e.g., recall, Field safety notice) reported in Germany. [Device short name] and similar devices is/are sold in Germany, hence the database is deemed relevant to collect applicable clinical risks for the S&P and AC objectives. |
| [MHRA Alerts, recalls and safety information: drugs and medical devices](https://www.gov.uk/drug-device-alerts) |  | X | X | “MHRA Alerts, recalls and safety information” is a database for field safety corrective actions reported in United Kingdom (UK). [Device short name] and similar devices is/are sold in UK, hence the database is deemed relevant to collect applicable clinical risks for the S&P and AC objectives. UK is no longer in EU but the population and clinical practices are representative of those in EU. The bias is not considered significant. |
| [SwissMedic – FSCA and recall](https://fsca.swissmedic.ch/mep/#/) |  | X | X | “SwissMedic – FSCA and recall” is a database for field safety corrective actions reported in Switzerland. [Device short name] and similar devices is/are sold in Switzerland, hence the database is deemed relevant to collect applicable clinical risks for the S&P and AC objectives. Switzerland is not in EU but the population and clinical practices are representative of those in EU. The bias is not considered significant. |
| [DAEN (Database of Adverse Event Notifications) - medical devices](https://apps.tga.gov.au/prod/DEVICES/daen-entry.aspx) |  | X | X | “DAEN” and “SARA” are databases for reporting of adverse events and recalls in Australia. Though the population involved and the procedure applied may differ as compared to the population and procedure in EU, this bias is not considered significant. [Device short name] and similar devices is/are sold in Australia, hence the databases are deemed relevant to collect applicable clinical risks for the S&P and AC objectives. |
| [SARA (System for Australian Recall Actions)](https://apps.tga.gov.au/PROD/SARA/arn-entry.aspx) |  | X | X |
| [Canadian recalls and safety alerts (advanced search)](https://recalls-rappels.canada.ca/en/search/site) |  | X | X | *Database with limited value as the period of search is not sufficiently detailed.*“Canadian Recalls and safety alerts” is the database to report recalls in Canada. Though the population involved and the procedure applied may differ as compared to the population and procedure in EU, this bias is not considered significant. [Device short name] and similar devices is/are sold in Canada, hence the database is deemed relevant to collect applicable clinical risks for the S&P and AC objectives. |
| [EUDAMED](https://ec.europa.eu/tools/eudamed/#/screen/home) | N/A | N/A | N/A | The database is not currently available. |
|  |  |  |

## Overall Search limitations

The search limitation methods may differ from a database to another. Hence, this section describes the overall search limitation strategy that has been applied in the vigilance/recall search.

Table 3: Overall search limitations (table adapted from the protocol)

| **Type of search** | **Objective** | **Type of limitation** | **Description** |
| --- | --- | --- | --- |
| Vigilance/recall search | AC | Search period:  | See Section 3 |
| S&P | Search period:  | See Section 3 |

## Inclusion and exclusion criteria

The result of vigilance / recall search is a list of events that is screened to determine if applicable to the subject device/equivalent device or similar devices (or alternative treatments when applicable). The justification for inclusion or exclusion will be documented as such in **Section 5**.

# Summary of vigilance/recall search results

## Introduction

The vigilance/recall search has been implemented according to the protocol described in **Section 1** to detect the clinical risks related to the subject or equivalent devices as well as similar devices (and/or alternative treatments when applicable), and bring clinical evidence for the demonstration of S&P of [device short name] and confirm the suitability of S&P AC.

## Search queries and results

### FDA MAUDE

The searches in FDA MAUDE database have been carried out by: John Doe

The searches in FDA MAUDE database have been implemented on: DD/MM/YYYY

The following table describes the search queries and number of results obtained in the FDA MAUDE database for the identification of vigilance relevant to [Device short name]/equivalent device and similar devices.

Table 4: Vigilance search queries in the FDA MAUDE database (adapted from the protocol)

| **Literature database** | **Objective** | **Query** | **General limitations** | **Keywords** | **Number of results** |
| --- | --- | --- | --- | --- | --- |
| [FDA MAUDE](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm) | AC |  | * Date Report Received by FDA: MM/DD/YYYY to MM/DD/YYYY
 | * Manufacturer:
* Brand Name:
* Product Code :

*Note: other fields are empty* |  |
| S&P |  | * Manufacturer:
* Brand Name:
* Product Code :

*Note: other fields are empty* |  |

The following results have been obtained.

Table 5: Vigilance search results in the FDA MAUDE database

| **Query** | **Report Number** | **Event Type** | **Manufacturer** | **Brand Name** | **Clinical risks found or Rationale for exclusion** |
| --- | --- | --- | --- | --- | --- |
| **N°** | **#** | **Device Problem** | **Patient Problem** |
| **Searches for AC** |
| 1 |  |  |  |  |  |  |  |
| 1 |  |  |  |  |  |  |  |
| **Searches for S&P** |
| 2 |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |

### FDA Medical Device Recalls

The searches in FDA Medical Device Recalls database have been carried out by: John Doe

The searches in FDA Medical Device Recalls database have been implemented on: DD/MM/YYYY

The following table describes the search queries and number of results obtained in the FDA Medical Device Recalls database for the identification of recalls relevant to [Device short name]/equivalent device and similar devices.

Table 6: Recall search queries in the FDA Medical Device Recalls database (adapted from the protocol)

| **Literature database** | **Objective** | **Query** | **General limitations** | **Keywords** | **Number of results** |
| --- | --- | --- | --- | --- | --- |
| [FDA Medical Device Recalls](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm) | AC |  | * Recall Date : MM/DD/YYYY to MM/DD/YYYY
 | * Product Name :
* Recalling Firm :
* Product Code :
* PMA/510(K) Number :

*Note: other fields are empty* |  |
| S&P |  | * Product Name :
* Recalling Firm :
* Product Code :
* PMA/510(K) Number :

*Note: other fields are empty* |  |

The following results have been obtained.

Table 7: Recall search results in the FDA Medical Device Recalls database

| **Query** | **Recall Number** | **Trade Name** | **Firm Name** | **Manufacturer Recall Reasons** | **Conclusion (i.e., device or patient problem) or Rationale for exclusion** |
| --- | --- | --- | --- | --- | --- |
| **N°** | **#** |
| **Searches for AC** |
| 1 |  |  |  |  |  |  |
| 1 |  |  |  |  |  |  |
| **Searches for S&P** |
| 2 |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |

### FDA TPLC

The searches in FDA TPLC database have been carried out by: John Doe

The searches in FDA TPLC database have been implemented on: DD/MM/YYYY

The following table describes the search queries and number of results obtained in the FDA TPLC database for the identification of vigilance/recalls relevant to devices with the same product code as [Device short name].

Table 8: Vigilance/recall search queries in the FDA TPLC database (adapted from the protocol)

| **Literature database** | **Objective** | **Query** | **General limitations** | **Keywords** | **Number of results** |
| --- | --- | --- | --- | --- | --- |
| [FDA TPLC](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm) | AC |  | * Since : YYYY
 | * Product Code :

*Note: other fields are empty* |  |

The following results have been obtained.

Table 9: Recall/Vigilance search results in the FDA MAUDE database

| **Query** | **Vigilance** | **Recall** |
| --- | --- | --- |
| **Device problem** | **Occurrence or exclusion rationale** | **Patient problem** | **Occurrence or exclusion rationale** | **Recall Number** | **Reason for Recall or exclusion rationale** |
| **Searches for AC** |
| 1 |  |  |  |  |  |  |
| 1 |  |  |  |  |  |  |
| 1 |  |  |  |  |  |  |
| 1 |  |  |  |  |  |  |
| 1 |  |  |  |  |  |  |
| 1 |  |  |  |  |  |  |
| 1 |  |  |  |  |  |  |
| 1 |  |  |  |  |  |  |
| 1 |  |  |  |  |  |  |
| 1 |  |  |  |  |  |  |

### ANSM Safety Information

The searches in ANSM Safety Information database have been carried out by: John Doe

The searches in ANSM Safety Information database have been implemented on: DD/MM/YYYY

The following table describes the search queries and number of results obtained in the ANSM Safety Information database for the identification of recalls relevant to [Device short name]/equivalent device and similar devices.

Table 10: Recall search queries in the ANSM Safety Information database (adapted from the protocol)

| **Literature database** | **Objective** | **Query** | **General limitations** | **Keywords** | **Number of results** |
| --- | --- | --- | --- | --- | --- |
| [ANSM safety information](https://ansm.sante.fr/informations-de-securite/) | AC |  | * Type : DEFAUT QUALITE, INFORMATION AUX UTILISATEURS, RAPPEL DE PRODUIT
* Produits de santé : Dispositifs médicaux
* Date : from DD/MM/YYYY to DD/MM/YYYY
 | * :

*Note: other fields are empty* |  |
| S&P |  | * :

*Note: other fields are empty* |  |

The following results have been obtained.

Table 11: Recall search results in the ANSM Safety Information database

| **Query** | **Safety Action Number** | **Manufacturer Name** | **Device Name** | **Description of problem** | **Conclusion (i.e., device or patient problem) or Rationale for exclusion** |
| --- | --- | --- | --- | --- | --- |
| **N°** | **#** |
| **Searches for AC** |
| 1 |  |  |  |  |  |  |
| 1 |  |  |  |  |  |  |
| **Searches for S&P** |
| 2 |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |

### Bfarm Field Corrective Actions

The searches in Bfarm Field Corrective Actions database have been carried out by: John Doe

The searches in Bfarm Field Corrective Actions database have been implemented on: DD/MM/YYYY

The following table describes the search queries and number of results obtained in the Bfarm Field Corrective Actions database for the identification of recalls relevant to [Device short name]/equivalent device and similar devices.

Table 12: Recall search queries in the Bfarm Field Corrective Actions database (adapted from the protocol)

| **Literature database** | **Objective** | **Query** | **General limitations** | **Keywords** | **Number of results** |
| --- | --- | --- | --- | --- | --- |
| [Bfarm Field Corrective Actions](https://www.bfarm.de/SiteGlobals/Forms/Suche/EN/Expertensuche_Formular.html?nn=708434&cl2Categories_Format=kundeninfo) | AC |  | * Category : Medical devices
* Product group of field corrective actions: *select or empty*
* Period: *select*
 | * Search item :

*Note: other fields are empty* |  |
| S&P |  | * Search item :

*Note: other fields are empty* |  |

The following results have been obtained.

Table 13: Recall search results in the Bfarm Field Corrective Actions database

| **Query** | **Reference** | **Manufacturer Name** | **Device Name** | **Description of problem** | **Conclusion (i.e., device or patient problem) or Rationale for exclusion** |
| --- | --- | --- | --- | --- | --- |
| **N°** | **#** |
| **Searches for AC** |
| 1 |  |  |  |  |  |  |
| 1 |  |  |  |  |  |  |
| **Searches for S&P** |
| 2 |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |

### MHRA Alerts, recalls and safety information

The searches in MHRA Alerts, recalls and safety information database have been carried out by: John Doe

The searches in MHRA Alerts, recalls and safety information database have been implemented on: DD/MM/YYYY

The following table describes the search queries and number of results obtained in the MHRA Alerts, recalls and safety information database for the identification of recalls relevant to [Device short name]/equivalent device and similar devices.

Table 14: Recall search queries in the MHRA Alerts, recalls and safety information database (adapted from the protocol)

| **Literature database** | **Objective** | **Query** | **General limitations** | **Keywords** | **Number of results** |
| --- | --- | --- | --- | --- | --- |
| [MHRA Alerts, recalls and safety information: drugs and medical devices](https://www.gov.uk/drug-device-alerts) | AC |  | * Message type : Field safety notice, Device safety information
* Medical specialty: *select or empty*
* Issued after: DD/MM/YYYY;
* Issued before: DD/MM/YYYY
 | * Search :

*Note: other fields are empty* |  |
| S&P |  | * Search :

*Note: other fields are empty* |  |

The following results have been obtained.

Table 15: Recall search results in the MHRA Alerts, recalls and safety information database

| **Query** | **Reference** | **Manufacturer Name** | **Device Name** | **Description of problem** | **Conclusion (i.e., device or patient problem) or Rationale for exclusion** |
| --- | --- | --- | --- | --- | --- |
| **N°** | **#** |
| **Searches for AC** |
| 1 |  |  |  |  |  |  |
| 1 |  |  |  |  |  |  |
| **Searches for S&P** |
| 2 |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |

### SwissMedic – FSCA and recall

The searches in SwissMedic – FSCA and recall database have been carried out by: John Doe

The searches in SwissMedic – FSCA and recall database have been implemented on: DD/MM/YYYY

The following table describes the search queries and number of results obtained in the SwissMedic – FSCA and recall database for the identification of recalls relevant to [Device short name]/equivalent device and similar devices.

Table 16: Recall search queries in the SwissMedic – FSCA and recall database (adapted from the protocol)

| **Literature database** | **Objective** | **Query** | **General limitations** | **Keywords** | **Number of results** |
| --- | --- | --- | --- | --- | --- |
| [SwissMedic – FSCA and recall](https://fsca.swissmedic.ch/mep/#/) | AC |  | * From; DD/MM/YYYY
* To: DD/MM/YYYY
 | * Please enter a search term:

*Note: other fields are empty* |  |
| S&P |  | * Please enter a search term:

*Note: other fields are empty* |  |

The following results have been obtained.

Table 17: Recall search results in the SwissMedic – FSCA and recall database

| **Query** | **Swissmedic Reference** | **Manufacturer**  | **Trade Name** | **Description of problem** | **Conclusion (i.e., device or patient problem) or Rationale for exclusion** |
| --- | --- | --- | --- | --- | --- |
| **N°** | **#** |
| **Searches for AC** |
| 1 |  |  |  |  |  |  |
| 1 |  |  |  |  |  |  |
| **Searches for S&P** |
| 2 |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |

### DAEN

The searches in DAEN database have been carried out by: John Doe

The searches in DAEN database have been implemented on: DD/MM/YYYY

The following table describes the search queries and number of results obtained in the DAEN database for the identification of vigilance relevant to [Device short name]/equivalent device and similar devices.

Table 18: Vigilance search queries in the DAEN database (adapted from the protocol)

| **Literature database** | **Objective** | **Query** | **General limitations** | **Keywords** | **Number of results** |
| --- | --- | --- | --- | --- | --- |
| [DAEN (Database of Adverse Event Notifications) - medical devices](https://apps.tga.gov.au/prod/DEVICES/daen-entry.aspx) | AC |  | * Select date range :
* From : YYYY Month DD
* To : YYYY Month DD
 | * Select medical devices :

*Note: other fields are empty* |  |
| S&P |  | * Select medical devices :

*Note: other fields are empty* |  |

The following results have been obtained.

Table 19: Vigilance search results in the DAEN database

| **Query** | **Report Number** | **Manufacturer** | **Trade Name** | **Event description** | **Conclusion (i.e., device or patient problem) or Rationale for exclusion** |
| --- | --- | --- | --- | --- | --- |
| **N°** | **#** |
| **Searches for AC** |
| 1 |  |  |  |  |  |  |
| 1 |  |  |  |  |  |  |
| **Searches for S&P** |
| 2 |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |

### SARA

The searches in SARA database have been carried out by: John Doe

The searches in SARA database have been implemented on: DD/MM/YYYY

The following table describes the search queries and number of results obtained in the SARA database for the identification of recalls relevant to [Device short name]/equivalent device and similar devices.

Table 20: Recall search queries in the SARA database (adapted from the protocol)

| **Literature database** | **Objective** | **Query** | **General limitations** | **Keywords** | **Number of results** |
| --- | --- | --- | --- | --- | --- |
| [SARA (System for Australian Recall Actions)](https://apps.tga.gov.au/PROD/SARA/arn-entry.aspx) | AC |  | * Select product type : Medical Device
* Select date range :
* From : YYYY Month DD
* To : YYYY Month DD
 | * Select products :

*Note: other fields are empty* |  |
| S&P |  | * Select products :

*Note: other fields are empty* |  |

The following results have been obtained.

Table 21: Recall search results in the SARA database

| **Query** | **TGA Recall Reference** | **Responsible Entity** | **Product Name** | **Reason/Issue** | **Conclusion (i.e., device or patient problem) or Rationale for exclusion** |
| --- | --- | --- | --- | --- | --- |
| **N°** | **#** |
| **Searches for AC** |
| 1 |  |  |  |  |  |  |
| 1 |  |  |  |  |  |  |
| **Searches for S&P** |
| 2 |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |

### Canadian Recalls and Safety Alerts

The searches in Canadian Recalls and Safety Alerts database have been carried out by: John Doe

The searches in Canadian Recalls and Safety Alerts database have been implemented on: DD/MM/YYYY

The following table describes the search queries and number of results obtained in the Canadian Recalls and Safety Alerts database for the identification of recalls relevant to [Device short name]/equivalent device and similar devices.

Table 22: Recall search queries in the Canadian Recalls and Safety Alerts database (adapted from the protocol)

| **Literature database** | **Objective** | **Query** | **General limitations** | **Keywords** | **Number of results** |
| --- | --- | --- | --- | --- | --- |
| [Canadian recalls and safety alerts (advanced search)](https://recalls-rappels.canada.ca/en/search/site) | AC |  | * Type: Recall
* Issue: Medical devices
* Last updated: YYYY
 | * Search:

*Note: other fields are empty* |  |
| S&P |  | * Search:

*Note: other fields are empty* |  |

The following results have been obtained.

Table 23: Recall search results in the Canadian Recalls and Safety Alerts database

| **Query** | **Identification Number** | **Companies** | **Product** | **Description of problem** | **Conclusion (i.e., device or patient problem) or Rationale for exclusion** |
| --- | --- | --- | --- | --- | --- |
| **N°** | **#** |
| **Searches for AC** |
| 1 |  |  |  |  |  |  |
| 1 |  |  |  |  |  |  |
| **Searches for S&P** |
| 2 |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |

# Summary of clinical risks

For the period of search indicated in **Section 3**, device problems and patients problems have been reported for the subject device/equivalent device (objective 3) and similar devices (objective 2), in the publicly available vigilance/recall databases.

The following sections will describe the summary of results obtained.

## Device problems

The following table presents the device problems reported for the subject device/equivalent device and similar devices.

Table 24: Device problems

| **Device problem** | **Occurrence** | **Comment** |
| --- | --- | --- |
| **Subject device: [Device short name]** |
|  |  |  |
|  |  |  |
| **Equivalent device: AAA** |
|  |  |  |
|  |  |  |
| **Similar device: XXX** |
|  |  |  |
|  |  |  |
| **Similar device: YYY** |
|  |  |  |

## Patient problems

The following table presents the patient problems reported for the subject device/equivalent device and similar devices.

Table 25: Patient problems

| **Patient problem** | **Occurrence** | **Comment** |
| --- | --- | --- |
| **Subject device: [Device short name]** |
|  |  |  |
|  |  |  |
| **Equivalent device: AAA** |
|  |  |  |
|  |  |  |
| **Similar device: XXX** |
|  |  |  |
|  |  |  |
| **Similar device: YYY** |
|  |  |  |