**Literature Search Report for AC**

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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# Table of Content

Contents

[Approval 2](#_Toc146186524)

[Revision History 3](#_Toc146186525)

[Table of Content 4](#_Toc146186526)

[Acronyms 5](#_Toc146186527)

[1. Objective 6](#_Toc146186528)

[2. Deviation to the protocol 6](#_Toc146186529)

[3. Search period 6](#_Toc146186530)

[4. Search databases 6](#_Toc146186531)

[4.1. Literature search database 6](#_Toc146186532)

[4.2. Clinical trials database 6](#_Toc146186533)

[4.3. Clinical evidence from the previous CER 7](#_Toc146186534)

[4.4. Inclusion and exclusion criteria 7](#_Toc146186535)

[5. Summary of literature search results 8](#_Toc146186536)

[5.1. Introduction 8](#_Toc146186537)

[5.2. Overall Search limitations 8](#_Toc146186538)

[5.3. Search queries 8](#_Toc146186539)

[5.4. Search results 11](#_Toc146186540)

[5.5. Reasons for exclusion 11](#_Toc146186541)

[6. Detailed literature search results 12](#_Toc146186542)

[7. List of retained citations for AC of S&P 12](#_Toc146186543)

# Acronyms

|  |  |
| --- | --- |
| AC | Acceptance criteria |
| CER | Clinical evaluation report |
| EBM | Evidence based medicine |
| EEA | European economic area |
| EU | European union |
| LVL | Level |
| MEDDEV | Medical Devices Documents |
| N/A | Not applicable |
| S&P | Safety and performance |
| US | United States |
| WHO | World health organization |

# Objective

The literature search report has been carried out according to the protocol [protocol number and revision]. A systematic approach has been applied to collect clinical literature articles that support the safety and performance (S&P) acceptance criteria (AC) for [Device Name], hereafter named [device short name] (Objective 2).

# 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 AC literature 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 databases

## Literature search database

The following literature databases have been selected to collect the published literature articles that support the S&P AC for [device short name].

Table 2: Search databases for published literature

| **Literature Database** | **Justification *(copy/paste the justification from the protocol)*** |
| --- | --- |
| [Embase](https://www.elsevier.com/solutions/embase-biomedical-research) | Embase is a recognized database for literature described in Section A4 of MEDDEV 2.7/1 rev.4.  Embase will be used as a primary medical literature database for the collection of clinical data using dedicated search terms. |
| [Pubmed](https://pubmed.ncbi.nlm.nih.gov/) | Pubmed is a recognized database for literature described in Section A4 of MEDDEV 2.7/1 rev.4.  Pubmed will be used as a primary medical literature database for the collection of clinical data using dedicated search terms |
| [Cochrane Library](https://www.cochranelibrary.com/) | The Cochrane Library includes a database of systematic reviews (Cochrane Reviews) in health care.  Cochrane Library is used as secondary database for the collection of clinical data missed in the primary databases to determine the S&P AC for the subject device. |
|  |  |

## Clinical trials database

The following clinical trials databases have been selected to collect the non-published data that support the S&P of [device short name].

Table 3: Search database for non-published data

| **Clinical Trial Database** | **Justification *(copy/paste the justification from the protocol)*** |
| --- | --- |
| [EU Clinical Trials Register](https://www.clinicaltrialsregister.eu/ctr-search/search) | The EU Clinical Trials Register contains information on interventional clinical trials on medicines conducted in the European Union (EU), or the European Economic Area (EEA). This database enables to search for clinical trials in the EudraCT database (used by national medicines regulators for data related to clinical trial protocols) and World Health Organization (WHO's) Registry Network (for which EU Clinical Trials Register is a primary registry. |
| [Clinicaltrials.gov](https://clinicaltrials.gov/) | Clinicaltrials.gov is the database of clinical trials conducted in US. |
|  |  |

## Clinical evidence from the previous CER

*To be removed if not applicable*

Literature articles included in the previous clinical evaluation report (CER) will be screened against the inclusion/exclusion criteria to verify their continuous suitability.

Table 4: Searches in previous CER

| **Previous CER** | **Number of articles to be screened** |
| --- | --- |
| *Document Number and revision* |  |
|  |
|  |
|  |  |
|  |
|  |

## Inclusion and exclusion criteria

For the identification of relevant literature articles, the results from the literature search implementation have been reviewed for inclusion based on the titles and abstracts (Level-1 screening) and the full articles (Level-2 screening). The decision to retain each article has been defined based on the inclusion/exclusion criteria described below.

Table 5: Inclusion/exclusion criteria for AC of S&P (copy/paste from the protocol)

| **Code** | **Description** |
| --- | --- |
| **Inclusion criteria** | |
| I1 | The article includes on label data on safety and/or performance of similar devices and alternative treatments |
| IX |  |
| **Exclusion criteria** | |
| E1 | The article does not include safety and/or performance data on similar devices and alternative treatments |
| E2 | The article includes off label data on safety and/or performance of similar devices and alternative treatments |
| E3 | When multiple medical conditions are treated/diagnosed or multiple devices are used during the same study, data are not stratified in respect to similar devices / alternative treatments or the medical condition treated/diagnosed by similar devices / alternative treatments. |
| E4 | Conference article, protocol, survey, position paper, case report, case series, reviews, non-controlled trial, non-randomized trial *(to be adapted depending on the quality and quantity of expected results)* |
| E5 | Not in English |
| E6 | Not in humans |
| E7 | Article outside the period of search |
| E8 | Duplicated reference |
| E9 | Full text not accessible |
| EX |  |

# Summary of literature search results

## Introduction

The literature search has been implemented according to the protocol described in **Section 1** to detect the published and unpublished articles related to devices similar to the subject device as well as alternative treatments, and bring clinical evidence for the definition of S&P AC that will be used for the demonstration of S&P of [device short name].

## Overall Search limitations

The search limitations, such as types of articles, language, etc. differ from a database to another. Hence, this section describes the overall search limitation strategy that has been applied in the literature search.

Table 6: Overall search limitations (table adapted from the protocol)

| **Type of search** | **Objective** | **Type of limitation** | **Description** |
| --- | --- | --- | --- |
| Literature search | AC | Search period:  Article type:  Language:  Population: | See Section 3  Controlled clinical Trials/meta-analysis/systematic review  English  Humans |

## Search queries

The literature search has been carried out by: John Doe

The literature search has been implemented on: DD/MM/YYYY

The following table describes the search queries that have been used for the identification of literature articles relevant to the AC of S&P for [Device short name].

Table 7: Search queries for AC of S&P (table adapted from the protocol (removal of strategy column))

***The queries need to be as detailed as possible with all limitations, start/end dates of search, exact keywords, connectors, etc. to be reproducible later by another author and to be modified easily for an update***

| **Literature database** | **Detailed limitations** | **#** | **Detailed query** |
| --- | --- | --- | --- |
| [Embase](https://www.elsevier.com/solutions/embase-biomedical-research) | EBM:   * Randomized controlled trial, * Controlled clinical trial, * Systematic review, * Meta-analysis   Date: Publication years from YYYY to YYYY  Quick limits:   * Humans, * Only in English   Publication types: Article |  |  |
|  |  |
|  |  |
| [Pubmed](https://pubmed.ncbi.nlm.nih.gov/advanced/) | Publication type:   * Comparative study * Controlled clinical trial * Meta analysis * Randomized controlled trial * Systematic review   Date – publication:  YYYY/MM/DD to YYYY/MM/DD  Language: English  Filter: Humans |  |  |
|  |  |
|  |  |
| [Cochrane Library](https://www.cochranelibrary.com/advanced-search) | Content type:   * Cochrane Review * Trials   Cochrane Library publication date:  Between Month YYYY and Month YYYY  Search word variations: activated |  | All Text: |
|  | All Text: |
|  | All Text: |
| [EU Clinical Trials Register](https://www.clinicaltrialsregister.eu/ctr-search/search) | Select Date Range: YYYY-MM-DD to YYYY-MM-DD  Results Status: Trials with results |  |  |
|  |  |
|  |  |
| [Clinicaltrials.gov](https://clinicaltrials.gov/) | Study status: All studies  Study type:   * Interventional * Observational   Study results: with results  Date Range: Last update posted: From MM/DD/YYYY to MM/DD/YYYY |  | Other terms: |
|  | Other terms: |
|  | Other terms: |
| Previous CER: XXX rev.1 | N/A – all articles included in the previous CER will be re-screened to confirm their suitability. | | |

## Search results

The following table describes the total number of articles collected after the implementation of each literature search query as well as the number of excluded/included articles after level-1 and level-2 screening processes.

Table 8: Search results

| **Literature database** | **Query** | **Number of results** | **Total number of results without duplicate** | **Total number of results** | **Level-1 screening** | | **Level-2 screening** | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Number of exclusions** | **Number included** | **Number of exclusions** | **Number included** |
| [Embase](https://www.elsevier.com/solutions/embase-biomedical-research) |  |  |  |  |  |  |  |  |
|  |  |
|  |  |
| [Pubmed](https://pubmed.ncbi.nlm.nih.gov/) |  |  |  |
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| [Cochrane Library](https://www.cochranelibrary.com/) |  |  |  |
|  |  |
|  |  |
| [Google Scholar](https://scholar.google.com/) |  |  |  |
|  |  |
|  |  |
| [EU Clinical Trials Register](https://www.clinicaltrialsregister.eu/ctr-search/search) |  |  |  |
|  |  |
|  |  |
| [Clinicaltrials.gov](https://clinicaltrials.gov/) |  |  |  |
|  |  |
|  |  |
| Previous CER: XXX rev.1 |  |  |  |

## Reasons for exclusion

The following table describes the summary of reasons for inclusion/exclusion for all articles collected via the literature search strategy implemented.

Table 9: Summary of reasons for inclusion/exclusion

| **TOTAL number of results** | **Level-1 screening** | | **Level-2 screening** | |
| --- | --- | --- | --- | --- |
| **Reasons for inclusion/exclusion** | **Number of results** | **Reasons for inclusion/exclusion** | **Number of results** |
|  | E1 |  | E1 |  |
| E2 |  | E2 |  |
| E3 |  | E3 |  |
| E4 |  | E4 |  |
| E5 |  | E5 |  |
| E6 |  | E6 |  |
| E7 |  | E7 |  |
| E8 |  | E8 |  |
| I1 |  | I1 |  |
| I2 |  | I2 |  |

# Detailed literature search results

The following table describes the reasons for inclusion/exclusion of all individual articles collected via the literature search strategy implemented.

Table 10: Justification for inclusion/exclusion

| **#** | **Citations** | **Screening** | |
| --- | --- | --- | --- |
| **LVL-1** | **LVL-2** |
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# List of retained citations for AC of S&P

1. XXX
2. XXX