**Literature search protocol**

**Product Name:** **{产品名称}**

***【本处填写产品名称，需要确保全篇技术文档及报告等的名称一致】***

**Model:** **{产品型号1}、{产品型号2}、{产品型号N}**

***【需要罗列本次认证的所有产品型号清单，如型号很多，可以采用另外附件文档的方式给出】***

**Document No.:** **{文件编号}**

***【本处填写本文件的编号】***

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{XXXX公司}

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**1.Background to the literature search and the literature review**

This section documents the importance of and rationale for the literature review:

* 1. **Device name/model**

Product Name: **{产品名称}**

Model: **{产品型号1}、{产品型号2}、{产品型号N}**

***【需要罗列本次认证的所有产品型号清单，如型号很多，可以采用另外附件文档的方式给出】***

* 1. **Importance of literature review to risk management process**

**{**文献评估对风险管理过程的重要性**}**

*（参考示例:*

*The literature review will provide data on current interventions for the intended patient population (state of the art) in order to give input to the assessments of acceptable benefit/risk profiles, what is currently considered as providing a high level of protection of health and safety and what are considered acceptable side-effects.）*

* 1. **Previous literature reviews**

{描述之前的文献评估}

* 1. **Importance of review to risk management process**

{审查对风险管理过程的重要性}

*（参考示例:*

*1)Risk/benefit analysis*

*If the residual risk is not judged acceptable using the criteria established in the risk management plan and further risk control is not practicable, the manufacturer may gather and review data and literature to determine if the medical benefits of the intended use outweigh the residual risk*

1. *Evaluation of overall residual risk acceptability*

*If the overall residual risk is not judged acceptable using the criteria established in the risk management plan, the manufacturer may gather and review data and literature to determine if the medical benefits of the intended use outweigh the overall residual risk;*

1. *Risk/benefit comparison*

*Direct comparison of risks and benefits is only valid if a common scale is used. When a common scale is used, the risk to benefit comparison can be evaluated quantitatively. Indirect risk/benefit comparisons do not use a common scale and are evaluated qualitatively. Whether quantitative or qualitative, risk/benefit comparisons can be Initially considered that a literature search for the hazard(s) and product class in question can provide significant insight into the ratio of benefit to risk.*

1. *Production and post-production monitoring）*
   1. **Previous literature searches conducted by the manufacturer**

{描述生产商之前的文献搜索}

* 1. **If including equivalent or benchmark devices, name and model of the devices**

{描述是否包括等同或基准设备，设备的名称和型号}

*（参考示例:*

|  |  |
| --- | --- |
| **Equivalent device 1** | Name: {等同器械名称}  Models: {等同器械型号}  Sizes: {等同器械尺寸}  components:{等同器械构成}  Software:{等同器械软件}  Accessories: {等同器械附件} |
| **Manufacturer** | {等同器械生产商} |
| **NB number** | {等同器械发证的CE公告机构编号} |
| **CE Certificate No.** | {等同器械的CE证书编号} |

|  |  |
| --- | --- |
| **Equivalent device N** | Name: {等同器械名称}  Models: {等同器械型号}  Sizes: {等同器械尺寸}  components:{等同器械构成}  Software:{等同器械软件}  Accessories: {等同器械附件} |
| **Manufacturer** | {等同器械生产商} |
| **NB number** | {等同器械发证的CE公告机构编号} |
| **CE Certificate No.** | {等同器械的CE证书编号} |

*）*

**1.7 The CER will need to establish equivalence to the device under evaluation or the relevance of benchmark devices to the clinical evaluation**

*The CER had establish equivalence to the device under evaluation, which can be referred to Clinical Evaluation Report.*

1. **Objective**

*（参考示例:*

*This section documents the research question(s), which is consistent with the scope of the clinical evaluation and carefully constructed using a process. The literature search and review is focused on the Population(s)/disease(s) or condition(s), Intervention(s), Comparator group(s)/control(s), Outcome(s)/endpoint(s). And the inputs for the review question(s) are the device description and the intended performance of the device including any claims on clinical performance and clinical safety which the manufacturer wants to use. Also information from the risk management process is needed as an input.*

*Objective of the literature review is following:*

*To demonstrate the actual device has achieving its intended use and performance during normal conditions of use and that the known and foreseeable risks, and any adverse events are minimised and acceptable when weighed against the benefits of the intended performance, and that any claims made about the device’s performance and safety are supported by suitable evidence.)*

1. **Scope of the literature search**

*（参考示例:*

*1) Intended purpose and application of the device;*

*2) Manufacturer’s specific claims about clinical performance and safety of device;*

*3)* *The significance of any risks that remain;*

*4) The data source and type of data to be used in the clinical evaluation.*

*5) Products/ models/ sizes/ settings and the technology on which the medical device is based)*

1. **Methods**

*（参考示例:*

*The methods section of the protocol documents the plans for literature search, study selection, data collection, and analysis methods. It defines the literature search strategy and the inclusion/exclusion criteria for the documents found.*

*The literature search protocol is following: )*

* 1. **Date of search**

The report should document the detailed date to conduct searching for the traceability.

* 1. **Name of person(s) undertaking the literature search and literature search methodology**

The literature search protocol is developed and executed by persons with expertise in information retrieval, having due regard to the scope of the clinical evaluation set out by the manufacturer. The searcher should help to optimize literature retrieval to identify all relevant published literature.

The importance of a literature search protocol is for critical appraisal of the methods. The search strategy should be based on carefully constructed review questions.

The report should be include the the persons information who conduct searcher and the personal CV.

* 1. **Period covered by search**

For comprehensive searching clinical data, the period covered by search is at least the relevant {填写搜索覆盖的年限} years, and should consider the development history of the technology involved in the actual device.

**4.4 The sources of data that will be used and a justification for their choice**

There are different sources of clinical literature that can be searched for clinical evaluation. For a comprehensive search , involving multiple databases. The search strategy should be documented and justified. Clinical literature Data searched is all taken from recognized scientific publications, in order to avoid publication bias, there are no Unpublished data. The sources of data that will be used and the justification for choice of sources are described below:

{填写选择搜索的数据库来源，以及选择的依据}

***【对于每一个选择的数据库，至少包需要提供信息，比如Sources of data、Extent of the searches、Justification for choice of sources 等】***

（参考示例:

**scientific databases – bibliographic**

**Sources of data**: MEDLINE Pubmed, CNKI, Science direct, Cochrane Library

**Extent of the searches**: Comprehensive

**Justification for** **choice of sources**: The MEDLINE Pubmed , CNKI and Science direct and Cochrane Library have plentiful documents for the general information about the clinical data. Science Direct and MEDLINE Pubmed are both high quality academic journal database. The [Cochrane Library](http://www.cochranelibrary.com/" \o "[Opens in new window] http://www.cochranelibrary.com/" \t "https://www.cochrane.org/about-us/_blank) is an online collection of six databases that contain different types of high-quality, independent evidence to inform healthcare decision-making, and a seventh database that provides information about Cochrane Groups. And CNKI is a large scale integration of information resources, so the rich contents and high quality resources is enough for our clinical evaluation. And the documents in MEDLINE Pubmed ,CNKI ,Science direct and Cochrane Library are enough for our clinical evaluation.)

## 4.5 Database search details

### 4.5.1 Search terms and their relationships and justification for search strategy--for clinical literature data

**1) Search terms and and their relationships**

{搜索词及其关系}

（参考示例:

| **Item** | **Keyword for international database** | **Keyword for Chinese database** |
| --- | --- | --- |
| {搜索词的类别}  *（参考示例:Keyword involved main function and Characteristics，keyword about manufacturer name of equivalent device)* | {国际数据库用到的搜索词} | {中国数据库用到的搜索词} |

)

1. **search strategy and justification for search strategy**

{搜索策略和搜索策略的理由}

**4.5.2 Search terms and their relationships and justification for search strategy--for clinical experience data**

1. **Search terms and and their relationships**

{搜索词及其关系}

（参考示例:

| **database** | **Keyword** | **justification for search strategy** |
| --- | --- | --- |
| {数据库名称}  *（参考示例:NMPA website，FDA website)* | {搜索词} | {搜索策略的理由} |

)

**2) search strategy and justification for search strategy**

Refer to the above table.

### 4.5.3 Medium used

All the data are searching online, and the search way as follow：

|  |  |  |  |
| --- | --- | --- | --- |
| **Data type** | **Source** | **Sources of data** | **access way** |
| {数据类型}*（参考示例:clinical literature data，clinical experience data)* | {数据来源}*（参考示例:adverse event and recall report databases)* | {数据源}*（参考示例:CNKI)* | {数据库路径}*（参考示例:<http://epub.cnki.net/kns/default.aspx>)* |

## 4.6 Selection/ exclusion criteria used to choose articles and justification for the choice

**4.6.1 For clinical literature data**

**Screening Processing:**

{简要描述数据筛选过程}

**The** **selection/exclusion criteria used for the screening literature is mainly following:**

**Include** **criteria:**

{描述数据入选准则}

**exclusion criteria:**

{描述数据排除准则}

**The justification for selection/exclusion criteria:**

{描述数据入选及排除准则的理由}

**4.6.2 For clinical experience data**

**Screening Processing:**

{简要描述数据筛选过程}

**The selection/exclusion criteria used for the screening experience data is mainly following:**

**Include criteria:**

{描述数据入选准则}

**exclusion criteria:**

{描述数据排除准则}

**The justification for selection/exclusion criteria:**

{描述数据入选及排除准则的理由}

Based on the above justification, we set the selection/exclusion criteria.

**4.7 Any deviations from the literature search protocol**

Any deviations from the literature search protocol should be noted in the literature search report.