

Appendix 3 – Literature Research and Review Protocol

Device name	
Date of the review	
Clinical indication	
Team members	
Clinical indication (PICO)	

Commented [AES1]: Include the name of the medical device or
[redacted]

Commented [AES2]: Include the name of the main clinical
[redacted]

Commented [AES3]: Include the names of the members of the
[redacted]

1. Previous literature reviews

Previous literature reviews

Commented [AES4]: List any previous literature reviews you
[redacted]

2. Objectives

No.	Search question
1	
2	

Commented [AES5]: Write in the questions to be asked during
literature research, based on the PICO process.
[redacted]

3. Methodology and data sources

3.1. Scientific databases

MEDLINE / PUBMED	[redacted]
EMBASE/ COHRANE	[redacted]
[redacted]	
[redacted]	

Commented [AES6]: These are scientific databases that are
most frequently used for literature research.
[redacted]

Commented [AES7]: Usually those are clinical trials,
[redacted]

Commented [AES8]: Usually those are review articles, meta-
[redacted]

3.1.1. Research time period

Date of research	
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Commented [AES9]: Write in the date(s)/time period when
[redacted]

[organization name]

Period covered by search

Commented [AES10]: Write in the period that is covered with

3.1.2. Keywords

Keywords

Commented [AES11]: Enter all keywords that you will

3.2. Medical device registries and databases

Name of the registry / database

Commented [AES12]: Write the name of the registry / database that you were using for the research. E.g. MAUDE, MHRA, BfArm, etc.

Date of search

Period covered by search

Commented [AES13]: Write in the period that is covered with

4. Literature research review

4.1. Scientific databases

Keyword(s)

Relevant articles

Relevant articles

Commented [AES14]: Write in the keywords used for

Commented [AES15]: In accordance with inclusion and

Commented [AES16]: Articles that answered the search

4.1.1. List of relevant articles

No.

Article reference

Type of the study

01

02

Commented [AES17]: List here all articles that you have found

Commented [AES18]: E.g., randomized study, clinical trial,

Commented [AES19]: Categorization from Table 1, section 4.2,

Commented [AES20]: Categorization from Table 2, section 4.2,

Commented [AES21]: Based on the appraisal of the criteria for suitability and data contribution, reviewed literature is categorized as:

•Level 1: Actual device

Commented [AES22]: This is just an example; adapt this

4.2. Appraisal of clinical data

Article no.

Appraisal Criteria for Suitability

Appraisal Criteria for Data Contribution

Category

Comment

Conclusion

01

