

<div style="border: 1px solid black; padding: 10px; text-align: center; color: red;"> Manufacturer Logo </div>	Literature Search Report Device Name	
	DOCUMENT NO:	REVISION NO:
	REVISION DATE: DD/MM/YYYY	EFFECTIVE DATE: DD/MM/YYYY

Literature Search Report

Device Name/ Model Name

Confidentiality Statement

This document contains trade secrets and commercial information that are privileged or confidential and may not be disclosed unless such disclosure is required by applicable law or regulations. In any event, persons to whom the information is disclosed must be informed that the information is privileged or confidential and may not be further disclosed by them. These restrictions on disclosure will apply equally to all future information supplied to you which is indicated as privileged or confidential.

<div style="border: 1px solid black; padding: 10px; text-align: center; color: red; font-weight: bold;">Manufacturer Logo</div>	Literature Search Report Device Name	
	DOCUMENT NO:	REVISION NO:
	REVISION DATE: DD/MM/YYYY	EFFECTIVE DATE: DD/MM/YYYY

Document Authorisation

Task	Name	Signature	Date
Document Prepared By	Enter the In-charge Person's Name	<div style="border: 1px solid black; padding: 10px; text-align: center; color: red;">Insert Signature</div>	DD-MM-YYYY
Document Reviewed By	Enter the In-charge Person's Name	<div style="border: 1px solid black; padding: 10px; text-align: center; color: red;">Insert Signature</div>	DD-MM-YYYY
Document Approved By	Enter the In-charge Person's Name	<div style="border: 1px solid black; padding: 10px; text-align: center; color: red;">Insert Signature</div>	DD-MM-YYYY

Revision History

Version	Release Date	Change History
Version Number	DD-MM-YYYY	Changes made on the particular release date mentioned in previous column.

Once printed, this document becomes **UNCONTROLLED**. User must verify latest version before each use.

Company Confidential

Page 2 of 4

<div style="border: 1px solid black; padding: 10px; text-align: center; color: red; font-weight: bold;">Manufacturer Logo</div>	Literature Search Report Device Name	
	DOCUMENT NO:	REVISION NO:
	REVISION DATE: DD/MM/YYYY	EFFECTIVE DATE: DD/MM/YYYY

Literature Search Report

The systematic literature report was conducted in alignment with the Literature Search Protocol delineated in the Clinical Evaluation Plan.

The search terms, limits, and criteria outlined in the protocol yielded a total of **XXXX** references. After eliminating duplicate entries (n=**XX**) originating from various combinations of search terms, **XXXX** articles were earmarked for additional assessment. A review of the titles and abstracts led to the exclusion of **XXXX** articles due to the following reasons:

- **Make a list of points that led to the exclusion of above-mentioned articles.**

Following these exclusions, **XX** articles underwent further evaluation and full-text assessment, resulting in the exclusion of an additional **XX** articles based on full-text exclusion criteria. Subsequently, **XX** articles underwent stage 02 and 03 appraisal, during which **XX** articles were eliminated due to failing to meet the eligibility criteria for these stages:

- **List out the criteria that were failed to meet by the eliminated articles, e.g. are mentioned below:**
- **Emphasis on a different intended clinical application not relevant to the device under evaluation.**
- **Lack of clinical data on the device.**

The final set comprised of **XX articles** which were thoroughly reviewed and appraised for the Clinical Evaluation Report (CER). For detailed insights into the literature filtering process, refer to Literature Review Analysis. The appraisal of the final selection of **XX** articles is presented below.

In the appraisal below, for each of the **XX** articles identified for appraisal and inclusion, the unique ID (which can be cross-referenced with the Literature Review Analysis), the title, year and study type for each article is extracted. Then, a summary of appraisal analysis and results is provided for review. Appraisal focused on extracting insights with regards to performance efficacy and risks to allow for an un-biased benefit-risk assessment in the context of the device under investigation. **Given that other similar devices already exist on the European market**, data collected on those devices with regards to the similar application and results as the device under investigation was relevant in the review.

All key findings are summarised and collectively analysed in the **mention the CER File name and version.**

<div style="border: 1px solid black; padding: 10px; text-align: center; color: red; font-weight: bold;">Manufacturer Logo</div>	Literature Search Report Device Name	
	DOCUMENT NO:	REVISION NO:
	REVISION DATE: DD/MM/YYYY	EFFECTIVE DATE: DD/MM/YYYY

Table 1: Summary of accepted literature Articles						
#	Unique ID	Title of Article	Study Type	Year	Appraisal and Analysis Report	Conclusion
1.	Mention the Unique ID of the paper.	Mention the Title of the article.	Mention the type of the study.	Mention the year of publishing.	Enter the appraisal and analysis report, include the abstract and methodology.	Mention the parameters measured and risks discussed in the conclusion section of the article.

Table 1. Summary of accepted literature Articles.