Literature Search Protocol

Device Name/ Model Name

Document Authorisation

Task	Name	Signature	Date
Document Prepared By	Enter the In-charge Person's Name	Insert Signature	DD-MM-YYYY
Document Reviewed By	Enter the In-charge Person's Name	Insert Signature	DD-MM-YYYY
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Revision History

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

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1. Introduction

This literature search protocol (LSP) has been developed to outline the procedures for the literature search and literature review for the Device Name, as manufactured by Name of the Manufacturer, and for devices presumed to be similar to this device. Some literature is available for the previous generation of the device, Mention the Name of the Previous Generation Device. This LSP addresses

additional literature identified by the manufacturer as a part of the CE Technical File.

2. Objective

The literature search is performed to establish clinical evidence referring to the clinical safety and performance of the Device Name. A comprehensive literature search to be conducted.

- Identify clinical performance and safety data not held by the manufacturer, and
- Identify and define the state of the art & current knowledge on currently available treatments involving mention the principle of working of the subject device and similar devices.

3. Methods

The methods described are based on the PRISMA guidelines. In case the literature search results in an unmanageable amount of literature, the literature search protocol will be updated as necessary. Changes to be made to the protocol will be outlined in the revision history of this document. Nevertheless, the aim of this document is to define a search strategy that can and will be used in the first attempt.

4. Device Description

4.1. Intended purpose & users

Summarize the medical purpose for which the device is intended, as per EU MDR definition.

4.2. Similar Devices and alternative techniques

Provide details on any similar or alternative techniques on the market or previous generations of the device. The aim is to establish any design or functional continuity and to show how past device iterations or similar models have influenced the current version.

5. Appraisal and Analysis plan

Provide details on how the gathered data will be evaluated and interpreted to assess the safety, performance, and clinical benefits of the device. This section is essential for ensuring that the literature search is rigorous and supports evidence-based conclusions in the Clinical Evaluation Report (CER).

6. Current knowledge/ State of the Art – literature review protocol

6.1. Data sources

List the databases used for the search (e.g., PubMed, Embase, Cochrane Library) and justify the selection.

6.2. Search limit

In a literature search report, **search limits** are criteria applied to refine and focus the search results to ensure relevance and quality. Under EU MDR, search limits help narrow the literature to studies most applicable to the medical device's clinical evaluation.

6.3. Search terms

Provide details of search terms used, including product-related keywords, clinical terms, and any limitations (e.g., date range, language).

6.4. Inclusion and Exclusion criteria

Define the criteria for including or excluding studies, considering aspects like study design, relevance to product, population, and language.

6.5. Assessment criteria

Describe the process for screening and selecting relevant studies, explaining the steps and criteria used.

7. References

Clinical Evaluation Report (Mention version) of Device Name in the QMS.