LITERATURE SEARCH PROTOCOL

**{{ device\_name }}**

EU Class: **{{ device\_class }}**

**Prepared Exclusively For**

{{ client.name }}

**{{ client.address }}**

**Prepared By**

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Cite Medical LLC

**Date**

**{{ date }}**

LITERATURE SEARCH

PROTOCOL

To Address the Requirement for GSPR as part of the technical documentation containing information to demonstrate the conformity with the Regulation (EU) 2017/745.

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# Overview

## Background

**{{ client.short }}** is conducting a scientific literature search to demonstrate the performance and safety of their devices and State of the Art devices.

The literature search will identify data not held by the manufacturer that are needed for the

clinical evaluation. The literature search will identify potential sources of clinical data for establishing:

* Clinical data relevant to the devices under evaluation and to the equivalent devices for which equivalency has been demonstrated
* Current knowledge/ the state of the art.

## Device Description

{{ device\_description }}

{{ image1.src }}

**{{ image1.caption} }**

# Stage 1 – Abstract Review

# Selection criteria

The following criteria is used to assess the suitability of material (articles, reports, etc.) for inclusion/exclusion in the analysis stage of this report.

## Inclusion Criteria

{{ for each inclusion\_criteria }}

[ as bullets ]

## Exclusion Criteria

{{ for each exclusion\_criteria }}

[ as bullets ]

Clinical literature was also excluded in situations where multiple papers appear to report on the same study. Consideration was given to the extent of duplication and reported safety or performance outcomes, prior to the excluding of any literature.

## Suitability Criteria – State of the Art

SoTA Suitability Criteria only applies to articles in the State-of-the-Art Search.

| Criteria | Description |
| --- | --- |
| CK0 | No SoTA information. |
| CK1 | Establishment of current knowledge/ the state of the art on the medical condition |
| CK2 | Establishment of current knowledge/ the state of the art on alternative therapies/treatments |
| CK3 | Determination and justification of criteria for the evaluation of the risk/benefit relationship |
| CK4 | Determination and justification of criteria for the evaluation of acceptability of undesirable side-effects |
| CK5 | Determination of equivalence |
| CK6 | Justification of the validity of surrogate endpoints |

*Table 1 Criteria for State of the Art*

## Suitability, Contribution, and Acceptability Criteria – Device

Suitability, Contribution, and Acceptability criteria apply to all articles in the safety/performance search.

| Suitability Criteria | Description | Grading System |
| --- | --- | --- |
| Appropriate device | Were the data generated from the device in question? | D1 Actual device  D2 Comparable device  D3 Other devices |

*Table 2 Criteria for Suitability*

# Scientific Databases

{{ for database in sci\_databases }}

## {{ database.db.name }}

{{ database.db.link }}

### Search Strategy

### Search Terms SoTA

{{ for item in database.sota\_terms }}

[ as bullets ]

### Search Terms S&P

{{ for item in database.sp\_terms }}

[ as bullets ]

Date: