**Clinical Evaluation Report**

For

[Device Name]

Manufacturer Name: [Manufacturer name]

Document Number: XXXX

Revision: XXXX

# Approval

**Author Approval**

|  |  |
| --- | --- |
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| Name: | Date: |
| Title: | Signature: |

**Evaluator Approval**

|  |  |
| --- | --- |
|  | |
| Name: | Date: |
| Title: | Signature: |
|  | |
| Name: | Date: |
| Title: | Signature: |

# Revision History

Table 1: History of revision

| **Revision** | **Date** | **Change History** |
| --- | --- | --- |
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# Acronyms

|  |  |
| --- | --- |
| AC | Acceptance criteria |
| ANSM | Agence nationale de sécurité du médicament et des produits de santé |
| Bfarm | Bundesinstitut für arzneimittel und medizinprodukte |
| B/R | Benefit/Risk |
| CAPA | Corrective action preventive action |
| CE | Conformitè europëenne |
| CEP | Clinical evaluation plan |
| CER | Clinical evaluation report |
| CI | Clinical investigation |
| CS | Common specifications |
| DAEN | Database of adverse event notifications |
| DoI | Declaration of interest |
| EMDN | European medical device nomenclature |
| EU | European union |
| FDA | Food and drug administration |
| FSCA | Field safety corrective action |
| GSPR | General safety and performance requirements |
| IFU | Instructions for use |
| LoE | Level of evidence |
| MAUDE | Manufacturer and user facility device experience |
| MDA | Active medical device |
| MDCG | Medical device coordinating group |
| MDD | Medical devices directive |
| MDN | Non-active medical device |
| MDR | Medical devices regulation |
| MEDDEV | Medical devices documents |
| MHRA | Medical and healthcare products regulatory agency |
| N/A | Not applicable |
| NB | Notified body |
| OPC | Objective performance criteria |
| PMCF | Post-market clinical follow-up |
| PMS | Post-market surveillance |
| PRISMA | Preferred reporting items for systematic reviews and meta-analyses |
| PSUR | Periodic safety update report |
| QMS | Quality management system |
| SARA | System for Australian recall actions |
| SoA | State of the art |
| SRN | Single registration number |
| SSCP | Summary of safety and clinical performance |
| S&P | Safety and performance |
| TD | Technical documentation |
| TPLC | Total product life cycle |
| UDI | Unique device identification |
| UDI-DI | UDI-Device identifier |
| WET | Well-established technology |

# Executive summary

This document is the initial /an update of clinical evaluation report under (EU) 2017/745 (MDR) for [Device name] (hereafter named [Device short name]) manufactured by [manufacturer name] (hereafter named [manufacturer short name]), for the purpose of compliance to the general safety and performance requirements (GSPR).

The device was previously CE marked under 93/42/EEC (MDD) as the device has been commercialized in the EU since YYYY.

[Device short name] is a sterile/non-sterile, single use / reusable, class I/Is/Im/Ir/IIa/IIb/III medical device indicated for XXX Copy the indication for use statement.

[Device short name] is XXXX Include a short device description.

The state of the art of the medical condition to be treated/diagnosed by [Device short name] has been established (see **Section 2.1**) and the alternative treatments and similar devices are the following:

* XXXX Target treatment
  + XXXX Similar device
  + XXXX Similar device
* XXXX Alternative treatment
* XXXX Alternative treatment

XXXX Include a summary of the conclusions that place the device within the treatment/diagnostic strategy of the medical condition.

A systematic clinical data search methodology has been developed to obtain a sufficient level of clinical evidence for the compliance to applicable GSPR for [Device short name]. The clinical evaluation is not based on the equivalence /is based on the equivalence with [Equivalent device name], manufactured by [equivalent device manufacturer name]. The following sources of clinical data have been included into the clinical evaluation:

* Premarket investigation: XX studies with a total number of Y patients
* Post-market clinical follow-up (PMCF) investigation: XX studies with a total number of Y patients
* Other PMCF activities: e.g., XXX survey received from Y patients/user
* Articles in the literature: XX articles with a total number of Y patients
* Post-market surveillance (PMS) activities: XXX sales over last Y years with WWW complaints received and ZZZ complaints reported to regulatory authorities.
* Preclinical data: [Device short name] complies with the of European harmonized, international or technical standards and Common Specifications (CS) recognized in Europe for the generic device type.

The safety and performance claims (see **Section 3.4.4**) as well as the clinical benefits (see **Section 3.4.5**) have been substantiated by sufficient clinical evidence and they met the acceptance criteria defined based on the state of the art.

As described in **Section 3.4.2,** all clinical risks identified in the clinical data collected have been mitigated as far as possible through the [Manufacturer short name]’s risk management process and the clinical residual risks have been delineated in the instructions for use through warnings, precautions, contra-indications, list of complications. All risks identified with a clinical impact (including side-effects) have been deemed acceptable in comparison to the state of the art, as indicated in **Section 3.4.3**. Finally, the overall benefit-risk profile of [Device short name] has been weighted in **Section 3.4.5** and the clinical data available confirm that the risks are acceptable when weighed against the intended benefits and are compatible with a high level of protection of health and safety taking into account the current knowledge and state of the art.

The following table summarizes how the requirements from MDCG 2020-13 have been addressed in the clinical evaluation report (CER).

Table 2: Traceability to requirements from clinical evaluation assessment report

| **CEAR Sections** | **Description** | **CER Sections** |
| --- | --- | --- |
| **Section A: Administrative particulars (notified body, manufacturer, product and clinical evaluation report reference)** | Medical device name model and type | Section 1.4 |
| Manufacturer(s) name and SRN | Section 1.2 |
| Notified body | Section 1.3 |
| Intended purpose | Section 1.6 |
| Check of clinical evaluation report authors | Section Approval and Appendix A – Evaluator qualifications and declaration of interest |
| Source documents | Section 1.11 |
| **Section B: Reviewers involved in the notified body assessment of the clinical evaluation** | N/A – requirements applicable to NBs | |
| **Section C: Device description, classification, clinical evaluation plan, information materials supplied by the manufacturer, common specifications and harmonised standards applied, equivalence and state of the art** | Device description | Section 1.5 |
| Classification | Section 1.4 |
| Device configurations/variants | Section 1.5 |
| Accessories or compatible devices | Section 1.4 |
| Previous generations of the device | Section 2.1.2 |
| Similar devices | Section 2.2 |
| Clinical evaluation plan | Section 1.11 |
| Clinical performance, safety and benefit claims | Sections 1.7 and 2.2.1.3 |
| Residual risks and any undesirable side- effects | Sections 1.6.4 and 1.6.5 |
| Common specifications and harmonized standards applied | Section 2.1.3 |
| Demonstration of equivalence | Section 3.1.2 |
| Access of data | Section 3.1 |
| State of the art | |
| * Benchmark devices, state of the art and other available treatment options | Section 2.1.7 |
| * Safety, performance and benefit-risk claims - requirements in terms of the state of the art | Section 2.2.1.3 |
| Novelty | Section 2.3.1 |
| **Section D: Clinical literature review** | Search criteria | Appendix D – Clinical data search protocol |
| Selection criteria | Appendix D – Clinical data search protocol |
| Literature search protocol | |
| * a brief summary of the literature search strategy | Section 3.3.3 |
| * systematic search and review methods | Appendix D – Clinical data search protocol |
| * Literature search documentation | Appendix D – Clinical data search protocol |
| Data appraisal | |
| * brief summary of data appraisal methods | Appendix B – Appraisal criteria |
| * appraisal results | Section 3.3.6 |
| **Section E: Clinical investigations and related documentation** | Detail of premarket clinical investigation | Section 3.3.1 |
| Report of premarket clinical investigation | Section Appendix C – Clinical / PMCF investigation protocols and reports |
| Detail of post-market clinical investigation | Section 3.3.2 |
| Clinical investigation plans | Section Appendix C – Clinical / PMCF investigation protocols and reports |
| **Section F: PMS, PMCF and the plan for updates** | Source documents | Section 1.11 |
| Justification for class III/implantable devices without CI (Article 61(4)) | Section 3.2.1 |
| Justification for absence of planned PMCF | Section 4 |
| Clinical evaluation updates | Section 4 |
| **Section G: IFU, SSCP, labelling and other information supplied with the device** | Source documents | Section 1.11 |
| Intended purpose | Section 1.6 |
| Intended patient population |
| Intended users |
| Limitations |
| Contraindications |
| Warnings and precautions |
| Adequacy of IFU with S&P data from CER | Section 3.4.2 |
| **Section H: Summary of all available data and conclusions** | CI on the device under evaluation | Section 3.3.1 |
| Equivalence data | Section 3.3.3 |
| Summary of safety | Sections 3.4.2 and 3.4.3 |
| Summary of performance | Section 3.4.4 |
| Sufficient level of evidence | Section 3.4.1 |
| Remaining questions | Section 3.4.5 |
| **Overall Conclusions** | Benefit-risk conclusion | Section 3.4.5 |
| Justification of risks | Section 3.4.3 |
| Adequacy between risks and CER | Section 3.4.2 |
| **Section I: Clinical evaluation consultation procedure for certain class III and class IIb devices (Article 54)** | N/A – requirements applicable to NBs – traceability to the results section 1.11 | |
| **Section J: Where demonstration of conformity based on clinical data is not deemed appropriate (Article 61[10])** | Justification for reliance upon Article 61(10) | Section 3.2 |
| Non-clinical data (performance, bench, pre-clinical evaluation) available | Section 3.3.1 |
| **Section K: The voluntary clinical consultation on the clinical development strategy (Article 61[2])** | Expert panel consultation reference | N/A – no consultation procedure performed |
| Expert panel recommendations |

# Scope of the Clinical Evaluation

## Introduction

The clinical evaluation report is performed to document [Device Short Name] meets the applicable GSPR for which clinical data are required. The clinical evaluation is intended to collect favorable and unfavorable clinical data related to [Device Short Name] and potential equivalent devices to support its safety and performance when used according to the manufacturer’s Instructions for Use (IFU) in a clinical setting taking into account the generally acknowledged state of the art. The clinical evaluation is conducted in compliance with MDR Article 61 and Annex XIV as well as the manufacturer’s clinical evaluation procedure [Doc], PMCF procedure [Doc] and clinical evaluation plan [Doc + Rev].

The clinical evaluation has been performed according to the following requirements:

* Article 61 and Annex XIV of (EU) 2017/745 (MDR)
* MEDDEV 2.7/1, Rev 4 (June 2016)
* MDCG 2019-15 rev.1 (December 2019) For class I only (remove, if not applicable)
* MDCG 2020-1 (March 2020) For software only ( remove, if not applicable)
* MDCG 2020-5 (April 2020) When equivalence is used (remove, if not applicable)
* MDCG 2020-6 (April 2020)
* MDCG 2024-10 (June 2024), For orphan devices only (remove, if not applicable)

## Manufacturer details

Table 3: Manufacturer information

|  |  |
| --- | --- |
| **Manufacturer name:** |  |
| **Manufacturer address:** |  |
| **SRN:** |  |

## Notified Body (NB) details

Table 4: NB information

|  |  |
| --- | --- |
| **NB name:** |  |
| **NB address:** |  |
| **Email contact:** |  |
| **Contact phone number:** |  |
| **NB number:** |  |

## Devices under evaluation

The devices in the scope of the clinical evaluation as described in the following table, are currently covered by the EU/CE Certificate under MDR/MDD (XXXXX).

OR

The devices in the scope of the clinical evaluation as described in the following table, have not yet been commercialized in the EU.

Table 5: Device details

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Device Trade Name** | |  | | | | |
| **Medical devices** | | | | | | |
| **Model Number** | **Basic UDI-DI** | **Description** | **EMDN Code** | **MDN Code** | **Class** | **Rule** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **Accessory for medical devices** | | | | | | |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

Justify the bundling of devices in a single CER

## Device description

The [Device Short name] is a Include a general description (Sourced from the TD)

The [Device Short name] is intended for Include intended use (Sourced from the IFU)

The [Device Short name] consists of Include mode of action (Sourced from the TD)

The [Device Short name] is illustrated in the following Figure(s):

Figure 1: [Device Short Name]

XXX

The following tables describe the general device characteristics of [Device Short name]. (Sourced from the TD)

Table 6: General device characteristics

|  |  |
| --- | --- |
| **Materials:** |  |
| **Sterility:** |  |
| **Main Mechanical characteristics:** |  |
| **Main Physicochemical characteristics:** |  |
| **Invasiveness:** |  |
| **Nature of contact:**  ***Identification of organs, tissues or body fluids contacted by the device*** |  |
| **Duration of use / nature of contact with the body:** |  |
| **Other** |  |

The [Device Short name] is available in various models for which the critical technical characteristics are the following:

Table 7: Critical device characteristics

| Device Model | … | … | … | … | … |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

Flag the special characteristics (that are critical and not common to all models) for which specific clinical evidence shall be collected in the CER (e.g., extreme sizes in the range, multiple indications, multiple populations, configurations):

Sufficient clinical evidence needs to cover the intended purpose as described in **Section 1.6** considering the indication(s), targeted patient(s), environment(s) of use, intended user(s), etc. Hence, the clinical evaluation will collect clinical evidence specific to the following intended use characteristics:

* XXXX Describe the critical characteristics of the intended purpose that needs to be substantiated by clinical data: e.g., indications (especially if multiple indications are claimed), patients (especially if there are multiple type of patients, e.g., pediatric, adult), the environment of use (e.g., ICU, home, etc.), the users (nurses, qualified surgeon, etc.), etc.

In addition, sufficient clinical evidence needs to cover all common device characteristics as well as specific device characteristics that are considered critical for the safety and performance of [device short name]. Those characteristics include:

* E.g., Round and square shapes
* E.g., Non-sterile / sterile devices
* E.g., Extreme sizes of the device range
* E.g., Animal tissue
* E.g., Models with specific connections

For configurable devices only. Finally, the subject device is composed of components that can be configured in multiple combinations. The possible configurations are described below with the justification of the critical ones that are representative of all combinations and will be clinically evaluated:

* XXX

## Intended purpose

### Indications

As specified in the IFU

### Targeted patient population

As specified in the IFU

### Contraindications

As specified in the IFU

### Warning and precautions

As specified in the IFU

### Undesirable side-effects

As specified in the IFU

## Clinical benefits and claims

The clinical benefits for [Device Short Name] as well as the claims of safety and performance are presented in the following table.

Table 8: Clinical benefits

| **Claims** | **Clinical claims** | **Non-clinical claims** | **Justification** |
| --- | --- | --- | --- |
| Benefits | | | |
|  | X |  |  |
|  |  | X |  |
| Performances | | | |
|  | X |  |  |
|  |  | X |  |
| Safety | | | |
|  | X |  |  |
|  |  | X |  |

**Section 3.4.4** and **Section 3.4.5** describe respectively how the data that support the S&P claims and the clinical benefits are met.

## Device history and geographic distribution

[Device Short Name] is a legacy/MDR device marketed in the EU under 93/42/EEC / (EU) 2017/745 since XXXX and has transitioned to MDR on DD/MM/YYYY.

Following the first commercialization/Since compliance to the MDR, the device has been modified several times as shown in the table below.

Table 9: History of changes

| **Design Change Number** | **Date of Implementation** | **Description** | **Clinical Impact** |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |

The changes identified in **bold** are those implemented since the last revision of the CER. As described, the clinical data collected before the implementation of changes are still applicable to the current [Device Short Name].

The following table represents the sales as well as the estimated number of uses in the countries or regions in which the device is commercialized including the year of first commercialization.

Table 10: Geographic repartition of sales

| **Country / Region** | **Year of first commercialization** | **Sale** | **Number of uses** |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

The following table describes the sales as well as the estimated number of uses per device model with the year of first commercialization.

Table 11: Sales per device model

| **Device models** | **Year of first commercialization** | **Sale** | **Number of uses** |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

## Applicable GSPR

Per Article 61, at least GSPRs 1 and 8 are required. Include solely the applicable GSPRs as identified in the GSPR checklist.

### GSPR 1

*Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.*

### GSPR 2

*The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.*

### GSPR 4

*Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, Manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority:*

1. *eliminate or reduce risks as far as possible through safe design and manufacture;*
2. *where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and*
3. *provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users.*

*Manufacturers shall inform users of any residual risks.*

### GSPR 6

*The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.*

### GSPR 8

*All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use.*

## Evaluator qualifications

[Manufacturer Short Name] has identified the following requirements for the evaluator(s):

* A degree from higher education in the respective field and five years of documented professional experience; or
* Ten years of documented professional experience if a degree is not a prerequisite for a given task.

The evaluator’s qualifications as well as the Declaration of Interest (DoI) are included in **Appendix A – Evaluator qualifications and declaration of interest**

## Inputs/Outputs of data generated and held by the manufacturer

The following documents generated by [Manufacturer Short Name] are inputs or outputs of the CER.

Table 12: Documents of reference (remove when non applicable)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Documents** | **Document Number** | **Input** | **Output** | **Comments** |
| Instructions for use | Doc + Rev | X | X |  |
| Risk management file | - | - | - | - |
| * Risk management plan | Doc + Rev | X | - |  |
| * Risk analysis | Doc + Rev | X | X |  |
| * Risk management report | Doc + Rev | X | X |  |
| Clinical evaluation plan (CEP) | Doc + Rev | X | - |  |
| PMCF Evaluation Report | Doc + Rev | X | - |  |
| PSUR/PMS report | Doc + Rev | X | - |  |
| PMCF Plan | Doc + Rev | - | X |  |
| PMS Plan | Doc + Rev | - | X |  |
| Technical Documentation (TD) | Doc + Rev | X | X |  |
| Summary of safety and clinical performance (SSCP) | Doc + Rev | - | X |  |
| Expert panel consultation reference | Doc + Rev | X | - |  |

The documents are available in the [Manufacturer Short Name]’s QMS and available under request.

In case of expert panel consultation procedure by manufacturer, describe the recommendation in this section.

# State of the art

A literature search strategy has been carried out to establish the current state of the art (SoA) of the medical conditions for which [device short name] is intended to be used. The strategy has been defined in the clinical data search protocol [Doc+Rev] and implemented in the literature search reports for SoA, [Doc+Rev], and for safety and performance (S&P) acceptance criteria (AC), [Doc+Rev], respectively in **Appendix D – Clinical data search protocol, Appendix E – Literature search report for SoA, Appendix F – Literature search report for acceptance criteria**.

The clinical evaluation is defined based on a methodologically sound procedure that also aims at providing a list of parameters and specifications to determine, based on the state of the art, the acceptability of the benefit-risk profile for [device short name]. As a result, **Section 2.1** summarizes the key information from the state of the art of medical conditions for which [device short name] is intended to be used and **Section 2.2** the clinical benefits, performance and safety outcome parameters and specifications defined based on similar devices/and therapeutic alternatives.

## Description of the state of the art

### State of the art literature search strategy and appraisal

The implementation of published literature searches resulted in the inclusion of XX published articles with the objective to establish the SoA (Objective 1) as described in **Appendix E – Literature search report for SoA.**

The following figure describes the selection process used.

Figure 2: Literature search results for SoA

Total Number of results

n=

Number of results without duplicates

n=

Number of results after Level I screening:

n=

Number of results after Level II screening:

n=

Figure to be completed as necessary.

All clinical evidence collected to describe the SoA has been evaluated Rank 6 per the appraisal criteria defined in **Appendix B – Appraisal criteria**.

### Historical context and development

To be defined based on the literature articles included for the SoA.

### Standards and guidance documents

To be defined based on the literature articles included for the SoA.

#### Standards

The following table describes the specific design and test standards recognized for the specific technology used with [Device short name].

Table 13: List of recognized

| **Standard** | **version** | **Title** |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| EN ISO 10993-1 | 2020 | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process |
| EN ISO 10993-5 | 2009 | Biological evaluation of medical devices - Tests for in vitro cytotoxicity |
| EN ISO 10993-10 | 2021 | Biological evaluation of medical devices - Tests for skin sensitization |
| EN ISO 10993-18 | 2020 | Biological evaluation of medical devices - Chemical characterization of medical device materials within a risk management process |
| EN ISO 10993-23 | 2021 | Biological evaluation of medical devices - Tests for irritation |
|  |  |  |
| EN ISO 14971 | 2019+A11:2021 | Medical devices - Application of Risk Management to Medical Devices |
| EN 62366-1 | 2015+A1:2020 | Medical devices - Application of usability engineering to medical devices |
|  |  |  |

#### Guidance documents

To be defined based on the literature articles included for the SoA.

The following table describes the professional guidelines recognized for the specific technology used with [Device short name].

Table 14: List of professional guidelines

| **Reference** | **version** | **Title** |
| --- | --- | --- |
|  |  |  |

### Description of medical condition and prevalence

To be defined based on the literature articles included for the SoA.

### Targeted user

To be defined based on the literature articles included for the SoA.

### Device concept

To be defined based on the literature articles included for the SoA.

### Description of alternative treatments

To be defined based on the literature articles included for the SoA.

### Benefits and risks of alternative treatments

To be defined based on the literature articles included for the SoA.

The benefits, risks, advantages, and disadvantages of all available alternative treatment options identified from

the SoA literature, are presented in the following table.

Table 15: B/R profiles of treatment options

| **Treatment options** | **Benefits** | **Risks** | **Advantages** | **Disadvantages** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

### Summary of recommendations from professional guidelines

To be defined based on the literature articles included for the SoA.

## Similar device

As part of the therapeutic alternatives, the following devices have been considered similar to [Device Short Name]. They have been deemed similar as they do not meet the clinical, technical and biological criteria as detailed in Annex XIV section 3 of the MDR but share a similar device technology under the same EMDN code and are intended to be used for the same indication and patient’s medical conditions, in the same environment and by the same type of user.

Table 16: Similar devices

| **Similar devices** | **Manufacturer Name** |
| --- | --- |
| **[similar device 1]** |  |
| **[similar device 2]** |  |
| … |  |

Optional As the parameters and specifications for the clinical benefits, safety and performance of [device short name] cannot be established solely based on similar devices, [Manufacturer short name] also considered the following therapeutic alternatives:

* XXX
* XXX

**Description of [similar device 1]**

Include a general description

A comparison between [device short name] and [similar device 1] is presented in the table below per the criteria described in MDCG 2020-5. A simplified version of the comparison table would also be acceptable.

Table 17: Comparison between [device short name] and [similar device 1]

| **Critical characteristics** | **Subject device** | **Similar device** |
| --- | --- | --- |
| Device Name | [device short name] | [similar device 1] |
| Device Manufacturer | [manufacturer short name] |  |
| CE marking |  |  |
| **Clinical criteria** | | |
| Intended purpose / indication for use |  |  |
| Clinical conditions |  |  |
| Disease treated (including severity / stage) |  |  |
| Application site |  |  |
| Patient population |  |  |
| User |  |  |
| Relevant clinical performance in view of expected clinical effect |  |  |
| *…* |  |  |
| **Technical criteria** | | |
| *Design characteristics (shape, size, etc.)* |  |  |
| *Physico-chemical properties (e.g. strength, viscosity)* |  |  |
| *Principle of use (e.g. deployment)* |  |  |
| *…* |  |  |
| **Biological criteria** | | |
| Body Contact |  |  |
| Material or substances |  |  |
| Duration of body contact |  |  |
| Release characteristics of substances (degradation product, leachable) |  |  |
| *…* |  |  |

### Summary and appraisal of clinical data on similar devices

#### Summary and appraisal of published and non-published clinical literature

The implementation of literature searches resulted in the inclusion of XX published articles with the objective to establish the safety and performance profile of similar devices/alternative treatment (objective 2) as described in **Appendix F – Literature search report for acceptance criteria**.

Figure 3: Literature search results for similar devices

Total Number of results

n=

Number of results without duplicates

n=

Number of results after Level I screening:

n=

Number of results after Level II screening:

n=

Figure to be completed as necessary.

The S&P information relevant to similar devices and/or therapeutic alternatives is summarized and appraised in the following table to establish their current safety and performance profiles.

The following table describes the study information, device and demographic characteristics for the articles specific to similar devices/therapeutic alternatives for the purpose to establish the acceptance criteria of safety and performance.

Table 19: Summary of published clinical literature used to establish the acceptance criteria

| **Article** | **Study type** | **Device characteristics** | | **Indication** | **Number of patients** | **Demographic characteristics** | | **Follow-up** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Device Name** | **Size** | **Age** | **Sex** |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

All articles have been appraised per the requirements described in **Appendix B – Appraisal criteria**. The following table describes the results of appraisal process:

Table 20: Appraisal of articles used to define the S&P AC

| **Article ref** | **MDCG 2020-6** | **Oxford LoE** | **Suitability** | | | | **Contribution** | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **D** | **A** | **P** | **R** | **T** | **O** | **F** | **S** | **C** |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |

Safety outcome parameters related to similar devices

The safety outcome parameters and specifications as discussed in the literature on similar devices/therapeutic alternatives are described in the following table.

Table 21: Summary of safety outcome parameters to establish the acceptance criteria

| **Article ref.** | **Safety outcome parameters** | **Results** | | | **Comments** |
| --- | --- | --- | --- | --- | --- |
| **Device** | **Timepoint** | **Specification** |
|  |  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |
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Performance outcome parameters related to similar devices

The performance outcome parameters and specifications as discussed in the literature on similar devices/therapeutic alternatives are described in the following table.

Table 22: Summary of performance outcome parameters to establish the acceptance criteria

| **Article ref.** | **Performance outcome parameters** | **Results** | | | **Comments** |
| --- | --- | --- | --- | --- | --- |
| **Device** | **Timepoint** | **Specification** |
|  |  |  |  |  |  |
|  |  |  |  |  |
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Clinical risks reported with similar devices

The following table describes the clinical risks identified in the articles collected on similar devices/therapeutic alternatives

Table 23: Summary of clinical risks to establish the acceptance criteria

| **Article ref.** | **Clinical risks** | **Results** | | | **Comments** |
| --- | --- | --- | --- | --- | --- |
| **Device** | **Timepoint** | **Rate** |
|  |  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |
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#### Summary and appraisal of external PMS database

Optional - This section can be useful when there is insufficient information in the literature to establish the acceptance criteria. E.g., generic devices, ancillary devices.

A search in vigilance and recall databases has been conducted to retrieve the clinical risks related to devices similar to [Device Short Name] (Objective 2). For the period from DD-MM-YYYY to DD-MM-YYYY, a total of XX vigilance and XX FSCA have been retrieved in the external PMS database consulted for the devices similar to [Device Short Name].

The protocol is available in **Appendix D – Clinical data search protocol**, and the report in **Appendix F – Literature search report for acceptance criteria.**

The results are appraised with a Rank 7 according to the criteria described in **Appendix B – Appraisal criteria**.

The following table presents the number of relevant events retrieved for all databases consulted.

Table 24: Results of vigilance/recall search implementation of similar devices

| **Database** | **Objective** | **Vigilance/recall search report** | **Number of results:** | | | | **Event type** | | | **FSCA** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Total** | **Excluded** | **Duplicate** | **Included** | **Device-related** | **Patient-related** | **Death** |
| FDA MAUDE | 2 |  |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |  |
| FDA Medical Device Recalls | 2 |  |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |  |
| FDA TPLC | 2 |  |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |  |
| ANSM safety information | 2 |  |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |  |
| Bfarm Field Corrective Actions | 2 |  |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |  |
| MHRA Alerts, recalls and safety information: drugs and medical devices | 2 |  |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |  |
| SwissMedic – FSCA and recall | 2 |  |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |  |
| DAEN (Database of Adverse Event Notifications) - medical devices | 2 |  |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |  |
| SARA (System for Australian Recall Actions) | 2 |  |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |  |
| Canadian recalls and safety alerts | 2 |  |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |  |
| **TOTAL** | |  |  |  |  |  |  |  |  |  |

The PMS review identified clinical risks and undesirable side-effects related to devices similar to [Device Short Name] as reported in the following table.

Table 25: Risks from public vigilance and recall databases

| **Events Reported** | **Event types** | **Occurrence** | | |
| --- | --- | --- | --- | --- |
| **Similar device 1** | **Similar device 2** | **Similar device 3** |
| Device-related risks |  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Patient-related risks (including undesirable Side-Effect) |  |  |  |  |
|  |  |  |  |
|  |  |  |  |

#### Summary and appraisal of SSCP clinical data

Only applicable to class III and implantable devices

For MDR class III and implantable devices, manufacturers are required to make publicly available the summary of safety and clinical performance (SSCP) via EUDAMED. Until EUDAMED becomes fully functional, SSCPs may be found on the websites of manufacturers or in other public locations.

A search has been implemented to find the SSCPs of MDR devices similar to [device short name] starting from EUDAMED and manufacturer websites.

The result of the search has been extracted to ensure the characterization of safety and performance of similar devices. The following SSCPs have been retrieved:

Table 26: Impact assessment of SSCP clinical data on similar devices

| **Similar device** | **Document number** | **Link to SSCP** |
| --- | --- | --- |
| XXXX (similar device) |  |  |
| XXXX (similar device) |  |  |

The following table describes the study information, device and demographic characteristics for SSCP clinical data specific to similar devices for the purpose of establishing their safety and performance profile.

Table 31: Summary of published clinical SSCP clinical data on similar devices

| **Title of clinical data** | **SSCP clinical data type** | **Device characteristics** | | **Indication** | **Number of patients** | **Demographic characteristics** | | **Follow-up** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Device Name** | **Size** | **Age** | **Sex** |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

All articles have been appraised per the requirements described in **Appendix 3 – Appraisal**. The following table describes the results of appraisal process:

Table 32: Appraisal of SSCP clinical data on similar devices

| **Clinical data ref** | **MDCG 2020-6** | **Oxford LoE** | **Suitability** | | | | **Contribution** | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **D** | **A** | **P** | **R** | **T** | **O** | **F** | **S** | **C** |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |

Safety outcome parameters related to similar devices

The safety outcome parameters and specifications as discussed in the SSCP clinical data on similar devices are described in the following table.

Table 33: Summary of safety outcome parameters on similar devices

| **Clinical data ref.** | **Safety outcome parameters** | **Results** | | | **Comments** |
| --- | --- | --- | --- | --- | --- |
| **Device** | **Timepoint** | **Specification** |
|  |  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |
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|  |  |  |  |  |  |

Performance outcome parameters related to similar devices

The performance outcome parameters and specifications as discussed in the SSCP clinical data on similar devices are described in the following table.

Table 34: Summary of performance outcome parameters on similar devices

| **Article ref.** | **Performance outcome parameters** | **Results** | | | **Comments** |
| --- | --- | --- | --- | --- | --- |
| **Device** | **Timepoint** | **Specification** |
|  |  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |
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|  |  |  |  |  |  |

Clinical risks reported with similar devices

The following table describes the clinical risks identified in the SSCP clinical data collected on similar devices.

Table 35: Summary of clinical risks on similar devices

| **Article ref.** | **Clinical risks** | **Results** | | | **Comments** |
| --- | --- | --- | --- | --- | --- |
| **Device** | **Timepoint** | **Rate** |
|  |  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |
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### Justification of safety and performance outcome parameters and acceptance criteria

Further to the review of SoA as described in **Section 2.2.1**, the following safety and performance outcome parameters have been considered relevant for the evaluation of S&P of [Device Short Name]:

Table 29: Retained S&P acceptance criteria

| **[Manufacturer short name]’s claims** | **Outcome parameters selected** | **Acceptance criteria** |
| --- | --- | --- |
| **Safety** | | |
|  |  |  |
| **Performance** | | |
|  |  |  |
| **Benefit** | | |
|  |  |  |

#### [Performance outcome parameter]

Justification of the relevance for the outcome parameter selected

Presentation of results obtained

| **Clinical data #** | **Device** | **Results** | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Timepoints** | | | | |
|  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

Conclude on the retained acceptance criteria.

#### [Safety outcome parameter]

Justification of the relevance for the outcome parameter selected

Presentation of results obtained

| **Clinical data #** | **Device** | **Results** | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Timepoints** | | | | |
|  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

Conclude on the retained acceptance criteria.

#### Clinical risks

Table 28: Clinical risks reported in the SoA customized the table as needed

| **Clinical risks** | **Device** | **Timepoints *when indicated*** | Results | | | | **Acceptance criteria retained**  *Or justification if not retained* |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Literature articles** | **Standards/OPC** | **Vigilance / recall database** | Overall range |
| *Include the AE, side-effects, device problems* |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
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|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

## Novelty & well-established technology

### Novelty

The novelty of [Device short name] has been evaluated for the criteria evaluated critical regarding safety and performance of the device with the consideration of clinical, technical and biological criteria as defined in Annex XIV of the MDR and described in the following table.

Table 30: Justification of novelty

|  |  |  |  |
| --- | --- | --- | --- |
| **Critical device characteristics** | **Any Novelty?** | **Description of novelty or justification for absence of novelty** | **Clinical impact of any novelty** |
| **Clinical characteristics** | | | |
| Medical purpose | Yes / No | If yes, specifically describe novel features  If no, provide evidence/justification to demonstrate non-novel features (e.g., based on similar devices) | If yes, describe the clinical impact and how this will be addressed in the CER  If no, indicate N/A – no novelty |
| Indications for use |  |  |  |
| Targeted type of procedure |  |  |  |
| Principles of operations |  |  |  |
| Condition of use |  |  |  |
| Targeted patients |  |  |  |
| Targeted users |  |  |  |
| Environment of use |  |  |  |
| Deployment Methods |  |  |  |
| … |  |  |  |
| **Technical characteristics** | | | |
| Design characteristics (e.g., shape, size, components) |  |  |  |
| Design characteristics (e.g., shape, size, components) |  |  |  |
| Mechanism of action |  |  |  |
| Device-Patient Interface |  |  |  |
| Compatibility with other devices |  |  |  |
| Manufacturing process |  |  |  |
| … |  |  |  |
| **Biological characteristics** | | | |
| Materials |  |  |  |
| Site of application |  |  |  |
| Duration of contact |  |  |  |
| … |  |  |  |
|  |  |  |  |
|  |  |  |  |

No novelty has been defined with [Device short name].

OR

The device includes the following novelty according to the current state of the art:

* XXXX
* XXXX
* XXXX

The novelty brought with [Device short name] has a significant/non-significant clinical impact because XXXX Include a summary the clinical impact of the novelty and how this will be addressed in the CER.

### Well-established technology (WET)

This section can be removed if the device does not meet the WET definition

MDCG 2020-6 defines a WET as a device in the category listed in Article 61(6b) as amended by Delegated Acts (Article 61(8)). The list currently includes sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors.

[Device short name] meets the definition of WET and is recognized as a device:

* with relatively simple, common and stable designs with little evolution.

Include the rationale

* with well-known clinical performance characteristics

Include the rationale

* with a long history on the market

Include the rationale

* belonging to a generic device group:
  + with a well-known safety not associated with safety issues in the past

Include the rationale

* + recognized standard of care devices where there is little evolution in indications and the state of the art.

Include the rationale

Conclusion for WET device

[Device short name] is part of the WET devices described in Article 61(6b) and meets the WET criteria in the definition of MDCG 2020-6. Hence the cumulative evidence from Rank 5 to Rank 12, including Rank 6 (i.e., clinical data (based on SoA) can be used to support the safety and performance of [Device short name]).

*/OR*

Conclusion for devices that are not in WET list but meet the definition.

Though [Device short name] is not part of the WET devices described in Article 61(6b), [Device short name] meets the WET definition described in MDCG 2020-6. Hence, the device is recognized in the current treatment strategy as defined in the state of the art for the treatment/diagnosis of XXXX Indicate the medical condition to be treated/diagnosed.

## SoA Conclusion

Include a summary of SoA with the positioning of the device type within the landscape of treatment options

# Device under evaluation

## Equivalent device

To support the safety and performance of [device short name], [manufacturer short name] has decided to consider a route of equivalence per MDR Article 61(5) with [Equivalent device name] manufactured by [Equivalent device manufacturer name]. [Equivalent Device Name] meets the criteria defined in Annex XIV section 3 of the MDR and [Manufacturer Short name] has a sufficient access to the data related [Equivalent Device Name] in order to justify the claims of equivalence as identified in **Table 31**.

The access of data to support the equivalence is granted through XXXX describe the method of access to data

As [device short name] is a class III /or implantable device and the equivalent device (certified under MDR) is not manufactured by [manufacturer short name], an agreement [Doc+Rev] has been signed between [manufacturer short name] and [equivalent device manufacturer name] to give full access to the technical documentation of [equivalent device name] on an ongoing basis. For class III/implantable devices only

/OR

No equivalence to other devices has been claimed for the demonstration of safety and performance of [device short name]. Remove the next subsections if no equivalence route is used.

### Equivalent device description

Equivalent device description

The following figure represents the [Equivalent Device Name]

Figure 4: Representative pictures of equivalent device

### Justification of equivalence

The following table considers the critical relevant characteristics for the purpose of comparing [Device Short Name] and its equivalent device based on clinical, technical and biological criteria as established in Annex XIV section 3 of the MDR and MDCG 2020-5.

Table 31: Justification of equivalence

| **Characteristics** | **[Device Name]** | **[Equivalent device name]** | **Identified differences or conclusion that there are no differences in the characteristic** | |
| --- | --- | --- | --- | --- |
| **Manufacturer Name** | [Manufacturer short name] | [Equivalent device short name] | N/A | |
| **Picture** |  |  | N/A | |
| **CE marking** |  |  |  | |
| 1. **Technical characteristics** | | | | |
| Indicate the critical design characteristics |  |  | No differences in the characteristic  OR short summary of the difference (refer to 1.X) | |
| Condition of use |  |  |  | |
| Indicate the critical specifications / technical features |  |  |  | |
| Principles of operation |  |  |  | |
| Other |  |  |  | |
| **Scientific justification why there would be no clinically significant difference in the safety and clinical performance of the device, OR a description of the impact on safety and or clinical performance** | | | | **Clinically significant difference**  **Yes / No** |
| 1.1. | | | |  |
| 1.2. | | | |  |
| 1. **Biological characteristics** | | | | |
| Materials in contact with the human tissue/body |  |  | No differences in the characteristic  OR short summary of the difference (refer to 2.X) | |
| Duration of contact |  |  |  | |
| Other (e.g., degradation characteristics if applicable) |  |  |  | |
| **Scientific justification why there would be no clinically significant difference in the safety and clinical performance of the device, OR a description of the impact on safety and or clinical performance** | | | | **Clinically significant difference**  **Yes / No** |
| 2.1. | | | |  |
| 2.2. | | | |  |
| 1. **Clinical characteristics** | | | | |
| Medical condition |  |  | No differences in the characteristic  OR short summary of the difference (refer to 3.X) | |
| Indication for use |  |  |  | |
| Targeted patients |  |  |  | |
| Intended users |  |  |  | |
| Indicate the critical performances with a medical effect |  |  |  | |
| **Scientific justification why there would be no clinically significant difference in the safety and clinical performance of the device, OR a description of the impact on safety and or clinical performance** | | | | **Clinically significant difference**  **Yes / No** |
| 3.1. | | | |  |
| 3.2. | | | |  |
| **Summary** | | | | |
| In the circumstance that more than one non-significant difference is identified, provide a justification whether the sum of differences may affect the safety and clinical performance of the device. | | | | |

The characteristics listed above are identical or similar to the extent that there would be no clinically significant difference in the safety and clinical performance of the device.

[Device Short name] and [Equivalence Device Name] are considered equivalent for the purpose of this CER.

## Level of clinical data required

### Exemption of clinical investigation only applicable to class III and implantable devices

Legacy device

[Device short name] is transitioning to the MDR but was lawfully placed on the market in accordance to the MDD. No common specifications have been published for the clinical evaluation of [device short name] /OR This clinical evaluation report has been defined based on the common specifications applicable to [device short name]. Finally, the clinical data currently available on [Device short name] are assumed to be sufficient and the conclusion of the clinical evaluation report will confirm this assumption.

As a result, according to Article 61(6a) of the MDR, no clinical investigation is evaluated required as long as there is sufficient clinical evidence on [device short name] to comply with the applicable GSPRs.

WET device

[Device short name] is considered to be a WET device as it meets the definition from MDCG 2020-6 as described in **Section 2.3.2** and is part of the list of WET in Article 61(6b) of the MDR. No common specifications have been published for the clinical evaluation of [device short name] /OR This clinical evaluation report has been defined based on the common specifications applicable to [device short name]. Finally, the clinical data currently available for the GSPR compliance of [Device short name] are assumed to be sufficient and the conclusion of the clinical evaluation report will confirm this assumption.

As a result, according to Article 61(6b) of the MDR, no clinical investigation is evaluated required as long as there is sufficient clinical evidence to comply with the applicable GSPRs.

Equivalent device with the same manufacturer

[Device short name] has been design by modifications of a device manufactured by [manufacturer short name] and both are considered equivalent per requirements from MDCG 2020-5 as described in **Section 3.1.2**. As a result [manufacturer short name] has defined a specific PMCF procedure to confirm the safety and performance of [Device short name] (see PMCF plan referenced in **Section 1.11**).

In conclusion, according to Article 61(4) of the MDR, no clinical investigation is evaluated required as long as there is sufficient clinical evidence on [Equivalent device name] to support the compliance of [device short name] with the applicable GSPRs.

Equivalent device with another manufacturer

As described in **Section 3.1.2**, [device short name] has been demonstrated to be equivalent to [Equivalent device name] not manufactured by [manufacturer short name] and currently commercialized in compliance to the MDR. **Section 3.1** provides the details of the contract in place that allows the [manufacturer short name] full access to the technical documentation of [Equivalent device name] on an ongoing basis.

As a result, according to Article 61(5) of the MDR, no clinical investigation is evaluated required as long as there is sufficient clinical evidence on [Equivalent device name] to support the compliance of [device short name] with the applicable GSPRs.

### Determination of minimum level of clinical data required

When article 61(10) applies

Article 61(1) of the MDR requires [Manufacturer short name] to justify the sufficient level of clinical evidence required to support the compliance to applicable GSPR. Using the criteria of Article 61(10), clinical data for [Device short name] were not deemed appropriate for the demonstration of conformity to GSPRs. The following table describes the justification drawn up by [Manufacturer short name]:

Table 32: Justification for meeting the criteria of Article 61(10)

| **Article 61(10) criteria** | **Justification** | **Conclusion** |
| --- | --- | --- |
| Results of the manufacturer's risk management |  | [Device short name] is a class I/Is/Im/Ir/IIa/IIb non-implantable device.  The risks resulting from the risk management activities are technical by nature and does not need to be substantiated by clinical data. |
| Interaction between the device and the human body |  | The interaction between the device and patients have been analyzed, are non-clinically significant and can be substantiated by non-clinical data. |
| Clinical performance intended |  | The review of performances claimed by the manufacturer did not emphasis any clinical performances leading to clinical benefits. All performances are technical by nature and does not need to be substantiated by clinical data |
| Claims of the manufacturer |  | [Manufacturer short name] does not have any claim  /  does not have any claim that needs to be substantiated by clinical data. All claims are technical by nature. |

If the rationale needs a long elaboration, the tabular format can be removed to include bullet points.

In conclusion, per the MDCG 2020-6 guidance document and considering [Device short name] meets the article 61(10) criteria, the minimum level of clinical evidence required will be from Rank 10 to 12, as applicable, with Rank 10 if common specifications have been published, with Rank 11 if preclinical tests with healthcare professionals/users are deemed required and Rank 12 for bench testing.

When article 61(10) does not apply

Article 61(1) of the MDR requires [Manufacturer short name] to justify the sufficient level of clinical evidence required to support the compliance to applicable GSPR. As described in the following table, MDCG 2020-6 Appendix III provides a suggested hierarchy of clinical evidence for the confirmation of conformity with applicable GSPRs under MDR.

Table 33: Hierarchy of clinical evidence under the MDR

| **Rank** | **Types of clinical data and evidence** |
| --- | --- |
| 1 | Results of high-quality clinical investigations covering all device variants, indications, patient populations, duration of treatment effect, etc |
| 2 | Results of high-quality clinical investigations with some gaps |
| 3 | Outcomes from high quality clinical data collection systems such as registries |
| 4 | Outcomes from studies with potential methodological flaws but where data can still be quantified and acceptability justified |
| 5 | Equivalence data (reliable / quantifiable) |
| 6 | Evaluation of state of the art, including evaluation of clinical data from similar devices |
| 7 | Complaints and vigilance data; curated data |
| 8 | Proactive PMS data, such as that derived from surveys |
| 9 | Individual case reports on the subject device |
| 10 | Compliance to non-clinical elements of common specifications considered relevant to device safety and performance |
| 11 | Simulated use / animal / cadaveric testing involving healthcare professionals or other end users |
| 12 | Pre-clinical and bench testing / compliance to standards |

Considering [device short name] is a legacy/MDR class X device, exempted from clinical investigation as described in **Section 3.2.1** only for class III/implantable devices, is/is not a well-established technology and the lack of novelty/or the novelty identified **Section 2.3.1**, [manufacturer short name] determined the minimum level of clinical evidence necessary to demonstrate the conformity to applicable GSPRs is:

* Rank X clinical evidence
* Rank Y clinical evidence
* Rank Z clinical evidence

**Section 3.4.1** of the clinical evaluation report will confirm if the clinical data available achieve the sufficient level of clinical evidence to support the safety and performance of [device short name] for the medical condition(s) for which the device is intended to be used.

To support the decision, see the suggested recommendations (to be customized with the device):

| **Scenario** | **Device class** | **Estimated minimum level of clinical evidence required** |
| --- | --- | --- |
| 1 | Class I/IIa/IIb meeting requirements from Article 61 (10) | Rank 10-12 (non-clinical evidence) |
| **Legacy devices or already commercialized MDR devices** | | |
| 2 | Class I (Is, Im, Ir)\* | Rank 10-12 (non-clinical evidence) +  Rank 7 (complaints and vigilance) |
| 3 | Class IIa non-implantable | Rank 10-12 (non-clinical evidence) +  Rank 7 (complaints and vigilance) +  Planned Rank 8 (PMCF activities, e.g., patient/user survey) |
| 4 | Class IIb non-implantable | Rank 10-12 (non-clinical evidence) +  Rank 7 (complaints and vigilance) +   * Rank 4 (data from subject device) or * Rank 5 (data from equivalent device2) +   + Planned Rank 8 (PMCF activities, e.g., patient/user survey) |
| 5 | Implantable/Class III | Rank 10-12 (non-clinical evidence) +  Rank 7 (complaints and vigilance) +   * Rank 4 (data from subject device) or * Rank 5 (data from equivalent device1) +   + Planned Rank 4 or higher (PMCF activities, e.g., PMCF study/investigation) |
| 6 | Implantable/Class III and WET | Rank 10-12 (non-clinical evidence) +  Rank 7 (complaints and vigilance) +  Rank 6 (data from similar devices) +   * Rank 4 (data from subject device) or * Rank 5 (data from equivalent device1) +   + Planned Rank 8 (PMCF activities, e.g., patient/user survey) |
| **New MDR devices** | | |
| 7 | Class I | Rank 10-12 (non-clinical evidence) +  Rank 5 (data from equivalent device) |
| 8 | Class I (Is, Im, Ir) and Class IIa non-implantable | Rank 10-12 (non-clinical evidence) +  Rank 5 (data from equivalent device) +   * Planned Rank 8 (PMCF activities, e.g., patient/user survey) |
| 9 | Class IIb non-implantable | Rank 10-12 (non-clinical evidence) +   * Rank 4 (clinical investigation), OR * Rank 5 (data from equivalent device) +   + Planned Rank 8 (PMCF activities, e.g., patient/user survey), or   + Planned Rank 4 or higher (PMCF activities, e.g., PMCF study/investigation) |
| 10 | Implantable/Class III | Rank 10-12 (non-clinical evidence) +   * Rank 4 (clinical investigation), OR * Rank 5 (data from equivalent device4) +   + Planned Rank 4 or higher (PMCF activities, e.g., PMCF study/investigation) |

## Summary and appraisal of clinical data for S&P

### Summary and appraisal of pre-clinical study

[Device short Name] was designed, manufactured, packaged and labeled according to harmonized, European or technical standards recognized for the device intended use. The description of tests and results are summarized in the following table.

Table 34:Pre-clinical testing

| **Description of Test** | **Testing Method (standards, CS)** | **Results** | **Testing Report** | **Appraisal** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
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|  |  |  |  |  |

[Device short Name] conforms with the technical state of the art recognized in Europe through compliance with the recognized standards and common specifications. The preclinical data are appraised Rank 10 and/or 11 and/or 12 according to MDCG 2020-6 as described in **Appendix B – Appraisal criteria**.

### Summary and appraisal of clinical investigation

X clinical investigations have been performed to demonstrate the safety and performance of [Device short name] that comprise:

* XXX
* XXX

The appraisal criteria used for the assessment of clinical investigation are described in **Appendix B – Appraisal criteria**.

The following table further describes the clinical investigation(s) performed.

Table 35: Clinical investigation summary and appraisal

| **Reference** | CI1 | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Identity of the investigation/study:** |  | | | | | | | | | |
| **Geography area:** | Indicate the country and if in EU (the applicable regulation when the study was conducted i.e., MDD/MDR). | | | | | | | | | |
| **Source:** | Provide link in EUDAMED, if not available, the link in the clinical trial database or the reference to the literature article. | | | | | | | | | |
| **Identity of the device:** | Including model(s) and version(s) | | | | | | | | | |
| **Intended use of the device:** |  | | | | | | | | | |
|  |  | | | | | | | | | |
| **Objectives:** |  | | | | | | | | | |
| **Study design:** | Randomized controlled trial, other pivotal trial, short-term feasibility study, other; | | | | | **Follow-up:** | | |  | |
| **Primary endpoint(s):** |  | | | | | | | | | |
| **Secondary endpoint(s):** |  | | | | | | | | | |
| **Inclusion criteria:** |  | | | | | **Exclusion criteria:** | | |  | |
| **Summary of method:** |  | | | | | | | | | |
|  | | | | | | | | | | |
| **Number of enrolled patients:** | Including if applicable in different treatment arms | | | | | | | | | |
| **Study population:** | Main baseline characteristics of each study group, including gender and age of enrolled subjects | | | | | | | | | |
|  | | | | | | | | | | |
| **Summary of results:** |  | | | | | | | | | |
| * **Performance endpoint(s)** | Table to be customized as needed   |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Performance endpoints*** | | | |  |  | Indicate results OR comparative results with p value | |  |  |  | | | | | | | | | | |
| * **Safety endpoint(s)** | Table to be customized as needed   |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Safety endpoints*** | | | |  |  | Indicate results OR comparative results with p value | |  |  |  | | | | | | | | | | |
| * **Adverse events and side-effects** | Table to be customized as needed   |  |  |  | | --- | --- | --- | | **Events** | **Number** | **Rate** | |  |  | Indicate rate in relation to time (e.g., PPY) | | | | | | | | | | |
|  | | | | | | | | | | |
| **Status:** | Complete  Ongoing (% of completeness of FU)  Complete but still ongoing for long-term FU | | | | | | | | | |
| **Limitations:** | high loss to follow-up, or potential confounding factors that may question the results. | | | | | | | | | |
| **Deficiency:** | Any device deficiency and any device replacements related to safety and/or performance during the study | | | | | | | | | |
|  | | | | | | | | | | |
| **Appraisal:** | **Rank:** |  | **LoE:** |  | **Suitability:** | |  | **Contribution:** | |  |

| **Reference** | CI2 | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Identity of the investigation/study:** |  | | | | | | | | | |
| **Geography area:** | Indicate the country and if in EU (the applicable regulation when the study was conducted i.e., MDD/MDR). | | | | | | | | | |
| **Source:** | Provide link in EUDAMED, if not available, the link in the clinical trial database or the reference to the literature article. | | | | | | | | | |
| **Identity of the device:** | Including model(s) and version(s) | | | | | | | | | |
| **Intended use of the device:** |  | | | | | | | | | |
|  |  | | | | | | | | | |
| **Objectives:** |  | | | | | | | | | |
| **Study design:** | Randomized controlled trial, other pivotal trial, short-term feasibility study, other; | | | | | **Follow-up:** | | |  | |
| **Primary endpoint(s):** |  | | | | | | | | | |
| **Secondary endpoint(s):** |  | | | | | | | | | |
| **Inclusion criteria:** |  | | | | | **Exclusion criteria:** | | |  | |
| **Summary of method:** |  | | | | | | | | | |
|  | | | | | | | | | | |
| **Number of enrolled patients:** | Including if applicable in different treatment arms | | | | | | | | | |
| **Study population:** | Main baseline characteristics of each study group, including gender and age of enrolled subjects | | | | | | | | | |
|  | | | | | | | | | | |
| **Summary of results:** |  | | | | | | | | | |
| * **Performance endpoint(s)** | Table to be customized as needed   |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Performance endpoints*** | | | |  |  | Indicate results OR comparative results with p value | |  |  |  | | | | | | | | | | |
| * **Safety endpoint(s)** | Table to be customized as needed   |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Safety endpoints*** | | | |  |  | Indicate results OR comparative results with p value | |  |  |  | | | | | | | | | | |
| * **Adverse events and side-effects** | Table to be customized as needed   |  |  |  | | --- | --- | --- | | **Events** | **Number** | **Rate** | |  |  | Indicate rate in relation to time (e.g., PPY) | | | | | | | | | | |
|  | | | | | | | | | | |
| **Status:** | Complete  Ongoing (% of completeness of FU)  Complete but still ongoing for long-term FU | | | | | | | | | |
| **Limitations:** | high loss to follow-up, or potential confounding factors that may question the results. | | | | | | | | | |
| **Deficiency:** | Any device deficiency and any device replacements related to safety and/or performance during the study | | | | | | | | | |
|  | | | | | | | | | | |
| **Appraisal:** | **Rank:** |  | **LoE:** |  | **Suitability:** | |  | **Contribution:** | |  |

In conclusion, X clinical investigations have been conducted to support the safety and performance of [Device short name] when used as intended and are classified Rank 1 (X studies), Rank 2 (X studies), Rank 3 (X studies) per the MDCG 2020-6 (April 2020). A total of X patients has been treated/diagnosed with an age from X to X years old. stratify the data as required if sub-indications/sub-populations are claimed.

The results obtained for the key safety and performance criteria defined to support the safety, performance and benefits claims as well as the qualitative and quantitative information related to clinical risks have been summarized in the following tables.

Table 36: Overall summary of clinical investigations

| **Key Outcome Parameters** | **Timepoints** | **Outcomes** |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |

Table 37: Overall summary of risks during clinical investigations

| **Clinical risks** | **Rate** |
| --- | --- |
| **Device-related risks** | |
|  |  |
| **Patient-related risks** | |
|  |  |

### Summary and appraisal of PMCF specific procedure

X PMCF investigations/studies have been performed to demonstrate the safety and performance of [Device short name] that comprise:

* XXX
* XXX

The appraisal criteria used for the assessment of PMCF activities are described in **Appendix B – Appraisal criteria**.

The following table further describes the PMCF investigations/studies performed.

Table 38: PMCF investigation summary and appraisal

| **Reference** | PMCF1 | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Identity of the investigation/study:** |  | | | | | | | | | |
| **Geography area:** | Indicate the country and if in EU (the applicable regulation when the study was conducted i.e., MDD/MDR). | | | | | | | | | |
| **Source:** | Provide link in EUDAMED, if not available, the link in the clinical trial database or the reference to the literature article. | | | | | | | | | |
| **Identity of the device:** | Including model(s) and version(s) | | | | | | | | | |
| **Intended use of the device:** |  | | | | | | | | | |
|  |  | | | | | | | | | |
| **Objectives:** |  | | | | | | | | | |
| **Study design:** | Randomized controlled trial, other pivotal trial, short-term feasibility study, other; | | | | | **Follow-up:** | | |  | |
| **Primary endpoint(s):** |  | | | | | | | | | |
| **Secondary endpoint(s):** |  | | | | | | | | | |
| **Inclusion criteria:** |  | | | | | **Exclusion criteria:** | | |  | |
| **Summary of method:** |  | | | | | | | | | |
|  | | | | | | | | | | |
| **Number of enrolled patients:** | Including if applicable in different treatment arms | | | | | | | | | |
| **Study population:** | Main baseline characteristics of each study group, including gender and age of enrolled subjects | | | | | | | | | |
|  | | | | | | | | | | |
| **Summary of results:** |  | | | | | | | | | |
| * **Performance endpoint(s)** | Table to be customized as needed   |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Performance endpoints*** | | | |  |  | Indicate results OR comparative results with p value | |  |  |  | | | | | | | | | | |
| * **Safety endpoint(s)** | Table to be customized as needed   |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Safety endpoints*** | | | |  |  | Indicate results OR comparative results with p value | |  |  |  | | | | | | | | | | |
| * **Adverse events and side-effects** | Table to be customized as needed   |  |  |  | | --- | --- | --- | | **Events** | **Number** | **Rate** | |  |  | Indicate rate in relation to time (e.g., PPY) | | | | | | | | | | |
|  | | | | | | | | | | |
| **Status:** | Complete  Ongoing (% of completeness of FU)  Complete but still ongoing for long-term FU | | | | | | | | | |
| **Limitations:** | high loss to follow-up, or potential confounding factors that may question the results. | | | | | | | | | |
| **Deficiency:** | Any device deficiency and any device replacements related to safety and/or performance during the study | | | | | | | | | |
|  | | | | | | | | | | |
| **Appraisal:** | **Rank:** |  | **LoE:** |  | **Suitability:** | |  | **Contribution:** | |  |

| **Reference** | PMCF2 | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Identity of the investigation/study:** |  | | | | | | | | | |
| **Geography area:** | Indicate the country and if in EU (the applicable regulation when the study was conducted i.e., MDD/MDR). | | | | | | | | | |
| **Source:** | Provide link in EUDAMED, if not available, the link in the clinical trial database or the reference to the literature article. | | | | | | | | | |
| **Identity of the device:** | Including model(s) and version(s) | | | | | | | | | |
| **Intended use of the device:** |  | | | | | | | | | |
|  |  | | | | | | | | | |
| **Objectives:** |  | | | | | | | | | |
| **Study design:** | Randomized controlled trial, other pivotal trial, short-term feasibility study, other; | | | | | **Follow-up:** | | |  | |
| **Primary endpoint(s):** |  | | | | | | | | | |
| **Secondary endpoint(s):** |  | | | | | | | | | |
| **Inclusion criteria:** |  | | | | | **Exclusion criteria:** | | |  | |
| **Summary of method:** |  | | | | | | | | | |
|  | | | | | | | | | | |
| **Number of enrolled patients:** | Including if applicable in different treatment arms | | | | | | | | | |
| **Study population:** | Main baseline characteristics of each study group, including gender and age of enrolled subjects | | | | | | | | | |
|  | | | | | | | | | | |
| **Summary of results:** |  | | | | | | | | | |
| * **Performance endpoint(s)** | Table to be customized as needed   |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Performance endpoints*** | | | |  |  | Indicate results OR comparative results with p value | |  |  |  | | | | | | | | | | |
| * **Safety endpoint(s)** | Table to be customized as needed   |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Safety endpoints*** | | | |  |  | Indicate results OR comparative results with p value | |  |  |  | | | | | | | | | | |
| * **Adverse events and side-effects** | Table to be customized as needed   |  |  |  | | --- | --- | --- | | **Events** | **Number** | **Rate** | |  |  | Indicate rate in relation to time (e.g., PPY) | | | | | | | | | | |
|  | | | | | | | | | | |
| **Status:** | Complete  Ongoing (% of completeness of FU)  Complete but still ongoing for long-term FU | | | | | | | | | |
| **Limitations:** | high loss to follow-up, or potential confounding factors that may question the results. | | | | | | | | | |
| **Deficiency:** | Any device deficiency and any device replacements related to safety and/or performance during the study | | | | | | | | | |
|  | | | | | | | | | | |
| **Appraisal:** | **Rank:** |  | **LoE:** |  | **Suitability:** | |  | **Contribution:** | |  |

X post-market clinical follow-up activities have been conducted to support the safety and performance of [Device short name] when used as intended and are classified Rank 1 (X studies), Rank 2 (X studies), Rank 3 (X studies), Rank 8 (X surveys) per the MDCG 2020-6 (April 2020). A total of X patients has been treated/diagnosed with an age from X to X years old. Stratify the data as required if sub-indications/sub-populations are claimed.

The results obtained for the key safety and performance criteria defined to support the safety, performance and benefits claims as well as the qualitative and quantitative information related to clinical risks have been summarized in the following tables.

Table 39: Overall summary of PMCF investigations/studies

| **Key Outcome Parameters** | **Timepoint** | **Outcomes** |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |

Table 40: Overall summary of risks during PMCF investigations/studies

| **Clinical risks** | **Rate** |
| --- | --- |
| **Device-related risks** | |
|  |  |
| **Patient-related risks** | |
|  |  |

### Summary and appraisal of published clinical literature

The implementation of literature searches resulted in the inclusion of XX articles with the objective to establish the safety and performance profile of [device short name] (objective 1) as described in **Appendix G – Literature search report for S&P**.

The following figure describes the selection process used.

Figure 5: Literature search results for [device short name]

Total Number of results

n=

Number of results without duplicates

n=

Number of results after Level I screening:

n=

Number of results after Level II screening:

n=

Figure to be completed

The results of each article are summarized in the following sections ordered based on the articles quality evaluated using the appraisal criteria defined in **Appendix B – Appraisal criteria**.

#### High quality articles

X articles of high quality have been collected to demonstrate the safety and performance of [Device short Name]. The appraisal criteria used for the assessment of articles are described in **Appendix B – Appraisal criteria**.

The following table further describes the articles of high-quality.

/OR No articles of high quality found

Table 41: Summary and appraisal of high-quality literature articles

| **Reference** |  | |
| --- | --- | --- |
| **Title:** |  | |
| **Appraisal criteria** | | |
| **Oxford Loe:** | LOE X | |
| **Suitability** | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Device** |  | **Application** |  | **Patient** |  | **Report** |  | | |
| **Contribution** | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Outcome** |  | **Follow-up** |  | **Statistics** |  | **Clinical significance** |  | | |
| **Rank (MDCG 2020-6)** | Rank 4 / Rank 5 | |
| **Appraisal conclusion** | High quality / low quality / off label use | |
| **Article description:** | | |
| **Objective:** |  | |
| **Method:** |  | |
| **FU:** |  | |
| **Statistics:** |  | |
| **Demographic data:** | **n=**XX | **Sex:** X males / Y females |
| **mean age:** (from X to Y years old)  describe in more details when necessary and when stratified data are available | **Medical indication:** XXX  Provide stratified data when necessary |
| **Device used:** | Include device name and characteristics when possible (e.g., size, model number, etc.) | |
| **Summary of results** | | |
| **Performance:** | |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Performance endpoints*** | | | |  |  | Indicate results OR comparative results with p value | |  |  |  | | |
| **Safety:** | |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Safety endpoints*** | | | |  |  | Indicate results OR comparative results with p value | |  |  |  | | |
| **Clinical risks:** | |  |  |  | | --- | --- | --- | | **Events** | **Number** | **Rate** | |  |  | Indicate rate in relation to time (e.g., PPY) | | |
| **Conclusion of the authors:** | | |
|  | | |

| **Reference** |  | |
| --- | --- | --- |
| **Title:** |  | |
| **Appraisal criteria** | | |
| **Oxford Loe:** | LOE X | |
| **Suitability** | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Device** |  | **Application** |  | **Patient** |  | **Report** |  | | |
| **Contribution** | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Outcome** |  | **Follow-up** |  | **Statistics** |  | **Clinical significance** |  | | |
| **Rank (MDCG 2020-6)** | Rank 4 / Rank 5 | |
| **Appraisal conclusion** | High quality / low quality / off label use | |
| **Article description:** | | |
| **Objective:** |  | |
| **Method:** |  | |
| **FU:** |  | |
| **Statistics:** |  | |
| **Demographic data:** | **n=**XX | **Sex:** X males / Y females |
| **mean age:** (from X to Y years old)  describe in more details when necessary and when stratified data are available | **Medical indication:** XXX  Provide stratified data when necessary |
| **Device used:** | Include device name and characteristics when possible (e.g., size, model number, etc.) | |
| **Summary of results** | | |
| **Performance:** | |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Performance endpoints*** | | | |  |  | Indicate results OR comparative results with p value | |  |  |  | | |
| **Safety:** | |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Safety endpoints*** | | | |  |  | Indicate results OR comparative results with p value | |  |  |  | | |
| **Clinical risks:** | |  |  |  | | --- | --- | --- | | **Events** | **Number** | **Rate** | |  |  | Indicate rate in relation to time (e.g., PPY) | | |
| **Conclusion of the authors:** | | |
|  | | |

#### Low-quality articles

X articles of low quality have been collected to demonstrate the safety and performance of [Device Short Name]. The appraisal criteria used for the assessment of articles are described in **Appendix B – Appraisal criteria**.

The following table further describes the articles of high-quality.

/OR No articles of high quality found

Table 42: Summary and appraisal of low-quality literature article

| **Reference** |  | |
| --- | --- | --- |
| **Title:** |  | |
| **Appraisal criteria** | | |
| **Oxford Loe:** | LOE X | |
| **Suitability** | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Device** |  | **Application** |  | **Patient** |  | **Report** |  | | |
| **Contribution** | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Outcome** |  | **Follow-up** |  | **Statistics** |  | **Clinical significance** |  | | |
| **Rank (MDCG 2020-6)** | Rank 4 / Rank 5 | |
| **Appraisal conclusion** | High quality / low quality / off label use | |
| **Article description:** | | |
| **Objective:** |  | |
| **Method:** |  | |
| **FU:** |  | |
| **Statistics:** |  | |
| **Demographic data:** | **n=**XX | **Sex:** X males / Y females |
| **mean age:** (from X to Y years old)  describe in more details when necessary and when stratified data are available | **Medical indication:** XXX  Provide stratified data when necessary |
| **Device used:** | Include device name and characteristics when possible (e.g., size, model number, etc.) | |
| **Summary of results** | | |
| **Performance:** | |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Performance endpoints*** | | | |  |  | Indicate results OR comparative results with p value | |  |  |  | | |
| **Safety:** | |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Safety endpoints*** | | | |  |  | Indicate results OR comparative results with p value | |  |  |  | | |
| **Clinical risks:** | |  |  |  | | --- | --- | --- | | **Events** | **Number** | **Rate** | |  |  | Indicate rate in relation to time (e.g., PPY) | | |
| **Conclusion of the authors:** | | |
|  | | |

| **Reference** |  | |
| --- | --- | --- |
| **Title:** |  | |
| **Appraisal criteria** | | |
| **Oxford Loe:** | LOE X | |
| **Suitability** | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Device** |  | **Application** |  | **Patient** |  | **Report** |  | | |
| **Contribution** | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Outcome** |  | **Follow-up** |  | **Statistics** |  | **Clinical significance** |  | | |
| **Rank (MDCG 2020-6)** | Rank 4 / Rank 5 | |
| **Appraisal conclusion** | High quality / low quality / off label use | |
| **Article description:** | | |
| **Objective:** |  | |
| **Method:** |  | |
| **FU:** |  | |
| **Statistics:** |  | |
| **Demographic data:** | **n=**XX | **Sex:** X males / Y females |
| **mean age:** (from X to Y years old)  describe in more details when necessary and when stratified data are available | **Medical indication:** XXX  Provide stratified data when necessary |
| **Device used:** | Include device name and characteristics when possible (e.g., size, model number, etc.) | |
| **Summary of results** | | |
| **Performance:** | |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Performance endpoints*** | | | |  |  | Indicate results OR comparative results with p value | |  |  |  | | |
| **Safety:** | |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Safety endpoints*** | | | |  |  | Indicate results OR comparative results with p value | |  |  |  | | |
| **Clinical risks:** | |  |  |  | | --- | --- | --- | | **Events** | **Number** | **Rate** | |  |  | Indicate rate in relation to time (e.g., PPY) | | |
| **Conclusion of the authors:** | | |
|  | | |

#### Off-label use

X articles on off label use have been collected to demonstrate the safety of [Device Short Name]. The appraisal criteria used for the assessment of articles are described in **Appendix B – Appraisal criteria**.

The following table further describes the articles with off label use.

Table 43: Summary and appraisal of off-label literature articles

| **Reference** |  | |
| --- | --- | --- |
| **Title:** |  | |
| **Appraisal criteria** | | |
| **Oxford Loe:** | LOE X | |
| **Suitability** | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Device** |  | **Application** |  | **Patient** |  | **Report** |  | | |
| **Contribution** | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Outcome** |  | **Follow-up** |  | **Statistics** |  | **Clinical significance** |  | | |
| **Rank (MDCG 2020-6)** | Rank 4 / Rank 5 | |
| **Appraisal conclusion** | High quality / low quality / off label use | |
| **Article description:** | | |
| **Objective:** |  | |
| **Method:** |  | |
| **FU:** |  | |
| **Statistics:** |  | |
| **Demographic data:** | **n=**XX | **Sex:** X males / Y females |
| **mean age:** (from X to Y years old)  describe in more details when necessary and when stratified data are available | **Medical indication:** XXX  Provide stratified data when necessary |
| **Device used:** | Include device name and characteristics when possible (e.g., size, model number, etc.) | |
| **Summary of results** | | |
| **Safety and Performance:** | N/A - Results of device evaluation regarding safety and performance endpoints are not analyzed for off label use articles. Only clinical risks observed are reviewed. | |
| **Clinical risks:** | |  |  |  | | --- | --- | --- | | **Events** | **Number** | **Rate** | |  |  | Indicate rate in relation to time (e.g., PPY) | | |
| **Conclusion of the authors:** | | |
|  | | |

| **Reference** |  | |
| --- | --- | --- |
| **Title:** |  | |
| **Appraisal criteria** | | |
| **Oxford Loe:** | LOE X | |
| **Suitability** | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Device** |  | **Application** |  | **Patient** |  | **Report** |  | | |
| **Contribution** | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Outcome** |  | **Follow-up** |  | **Statistics** |  | **Clinical significance** |  | | |
| **Rank (MDCG 2020-6)** | Rank 4 / Rank 5 | |
| **Appraisal conclusion** | High quality / low quality / off label use | |
| **Article description:** | | |
| **Objective:** |  | |
| **Method:** |  | |
| **FU:** |  | |
| **Statistics:** |  | |
| **Demographic data:** | **n=**XX | **Sex:** X males / Y females |
| **mean age:** (from X to Y years old)  describe in more details when necessary and when stratified data are available | **Medical indication:** XXX  Provide stratified data when necessary |
| **Device used:** | Include device name and characteristics when possible (e.g., size, model number, etc.) | |
| **Summary of results** | | |
| **Safety and Performance:** | N/A - Results of device evaluation regarding safety and performance endpoints are not analyzed for off label use articles. Only clinical risks observed are reviewed. | |
| **Clinical risks:** | |  |  |  | | --- | --- | --- | | **Events** | **Number** | **Rate** | |  |  | Indicate rate in relation to time (e.g., PPY) | | |
| **Conclusion of the authors:** | | |
|  | | |

#### Overall conclusion regarding literature articles

A total of X literature articles has been found to support the safety and performance of [Device short name] including X articles of high quality and X articles of low quality. In addition, X articles have been found for off-label uses.

X articles are Rank 4 on [Device short name] and X articles are Rank 5 on a device equivalent to [Device short name] per MDCG 2020-6 (April 2020).

A total of X patients has been treated/diagnosed with an age from X to X years old. Please stratify the data as required if sub-indications/sub-populations are claimed.

The results obtained for the key criteria defined to support the safety, performance and benefits claims as well as the qualitative and quantitative information related to clinical risks have been summarized in the following tables.

Table 44: Overall summary of literature articles

| **Key Outcome Parameters** | **Timepoint** | **Outcomes** |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |

Table 45: Overall summary of risks in literature articles

| **Clinical risks** | **Rate** |
| --- | --- |
| **Device-related risks** | |
|  |  |
| **Patient-related risks** | |
|  |  |

### Summary and appraisal of external PMS database

Please remove the section if no PMS database is queried.

A search in vigilance and FSCA databases has been conducted to retrieve the clinical risks related to [Device Short Name]. For the period from DD-MM-YYYY to DD-MM-YYYY, a total of XX vigilance and XX FSCA have been retrieved in the external PMS database consulted for the [Device short name] or its equivalent device.

The protocol and report are respectively **Appendix D – Clinical data search protocol** and **Appendix H – Vigilance/recall search report.**

The results are appraised with a Rank 7 according to the criteria described in **Appendix B – Appraisal criteria**.

The following table presents the number of relevant events retrieved for all databases consulted.

Table 46: Results of vigilance/recall search implementation of subject device

| **Database** | **Objective** | **Vigilance/recall search report** | **Number of results:** | | | | **Event type** | | | **FSCA** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Total** | **Excluded** | **Duplicate** | **Included** | **Device-related** | **Patient-related** | **Death** |
| FDA MAUDE | 3 |  |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |  |
| FDA Medical Device Recalls | 3 |  |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |  |
| FDA TPLC | 3 |  |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |  |
| ANSM safety information | 3 |  |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |  |
| Bfarm Field Corrective Actions | 3 |  |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |  |
| MHRA Alerts, recalls and safety information: drugs and medical devices | 3 |  |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |  |
| SwissMedic – FSCA and recall | 3 |  |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |  |
| DAEN (Database of Adverse Event Notifications) - medical devices | 3 |  |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |  |
| SARA (System for Australian Recall Actions) | 3 |  |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |  |
| Canadian recalls and safety alerts | 3 |  |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |  |
| **TOTAL** | | All |  |  |  |  |  |  |  |  |

The vigilance and recall review identified clinical risks including undesirable side-effects related to [Device Short Name], or its equivalent device as reported in the following table.

Table 47: Risks from public vigilance/recall databases

| **Events Reported** | **Event types** | **Occurrence** | |
| --- | --- | --- | --- |
| **Subject device** | **Equivalent device** |
| Device-related risks |  |  |  |
|  |  |  |
|  |  |  |
| Patient-related risks |  |  |  |
|  |  |  |
|  |  |  |

### Summary and appraisal of SSCP clinical data of equivalent devices

Only applicable to class III and implantable equivalent devices

For MDR class III and implantable devices, manufacturers are required to make publicly available the summary of safety and clinical performance (SSCP) via EUDAMED. Until EUDAMED becomes fully functional, SSCPs may be found on the websites of manufacturers or in other public locations.

A search has been implemented to find the SSCPs of MDR devices equivalent to [device short name] starting from EUDAMED and manufacturer websites.

The result of the search has been extracted to ensure the characterization of safety and performance of equivalent devices. The following SSCPs have been retrieved:

Table 26: Impact assessment of SSCP clinical data on equivalent devices

| **Equivalent device** | **Document number** | **Link to SSCP** |
| --- | --- | --- |
| XXXX |  |  |
| XXXX |  |  |

The following table describes the study information, device and demographic characteristics for SSCP clinical data specific to equivalent devices for the purpose of establishing their safety and performance profile.

Table 31: Summary of published clinical SSCP clinical data on equivalent devices

| **Title of clinical data** | **SSCP clinical data type** | **Device characteristics** | | **Indication** | **Number of patients** | **Demographic characteristics** | | **Follow-up** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Device Name** | **Size** | **Age** | **Sex** |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

All articles have been appraised per the requirements described in **Appendix 3 – Appraisal**. The following table describes the results of appraisal process:

Table 32: Appraisal of SSCP clinical data on equivalent devices

| **Clinical data ref** | **MDCG 2020-6** | **Oxford LoE** | **Suitability** | | | | **Contribution** | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **D** | **A** | **P** | **R** | **T** | **O** | **F** | **S** | **C** |
|  | Rank 6 |  |  |  |  |  |  |  |  |  |  |
|  | Rank 6 |  |  |  |  |  |  |  |  |  |  |

Safety outcome parameters related to equivalent devices

The safety outcome parameters and specifications as discussed in the SSCP clinical data on equivalent devices are described in the following table.

Table 33: Summary of safety outcome parameters on equivalent devices

| **Clinical data ref.** | **Safety outcome parameters** | **Results** | | | **Comments** |
| --- | --- | --- | --- | --- | --- |
| **Device** | **Timepoint** | **Specification** |
|  |  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |
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Performance outcome parameters related to equivalent devices

The performance outcome parameters and specifications as discussed in the SSCP clinical data on equivalent devices are described in the following table.

Table 34: Summary of performance outcome parameters on equivalent devices

| **Article ref.** | **Performance outcome parameters** | **Results** | | | **Comments** |
| --- | --- | --- | --- | --- | --- |
| **Device** | **Timepoint** | **Specification** |
|  |  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |
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|  |  |  |  |  |  |

Clinical risks reported with equivalent devices

The following table describes the clinical risks identified in the SSCP clinical data collected on equivalent devices.

Table 35: Summary of clinical risks on equivalent devices

| **Article ref.** | **Clinical risks** | **Results** | | | **Comments** |
| --- | --- | --- | --- | --- | --- |
| **Device** | **Timepoint** | **Rate** |
|  |  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |
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### Summary and appraisal of internal PMS data

The PMS data resulting from the PSUR/PMS report (see **Section 1.11**) and especially, the sales, complaints and vigilance, are summarized to emphasize the device and patient-related risks for the [Device short name].

The following findings have been identified in the PSUR/PMS report (see **Section 1.11**):

* XXX Identify the conclusion of the PSUR/PMS report for corrective action,
* XXX Identify the conclusion of the PSUR/PMS report regarding the need to update the CER,
* XXX Identify the conclusion of the PSUR/PMS report regarding trend analysis,
* XXX Identify the conclusion of the PSUR/PMS report regarding the reporting to authorities

The PMS data are appraised Rank 7 per the criteria described in **Appendix B – Appraisal criteria.**

The following tables present an overview of PMS data available for the period from XX/XX/XXXX to XX/XX/XXXX.

Table 48: Complaints and vigilance per year

| **Year** | **World-Wide** | | | | | **Europe** | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Sales** | **Complaints** | | **Vigilance** | | **Sales** | **Complaints** | | **Vigilance** | |
| **n** | **rate** | **n** | **rate** | **n** | **rate** | **n** | **rate** |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

Table 49: Complaints and vigilance per model if several Basic UDI-DI/models involved

| **Model** | **World-Wide** | | | | | **Europe** | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Sales** | **Complaints** | | **Vigilance** | | **Sales** | **Complaints** | | **Vigilance** | |
| **n** | **rate** | **n** | **rate** | **n** | **rate** | **n** | **rate** |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

Table 50: Type of device problem

| **Device problem** | **Region** | **YYYY** | **YYYY** | **YYYY** | **YYYY** |
| --- | --- | --- | --- | --- | --- |
| **Reported incidents** | | | | | |
|  | EU |  |  |  |  |
| WW |  |  |  |  |
|  | EE |  |  |  |  |
| WW |  |  |  |  |
| **Non-serious incident – Known undesirable side-effects** | | | | | |
|  | EU |  |  |  |  |
| WW |  |  |  |  |
|  | EU |  |  |  |  |
| WW |  |  |  |  |

Table 51: Type of patient problem

| **Type of patient problem** | **Region** | **YYYY** | **YYYY** | **YYYY** | **YYYY** |
| --- | --- | --- | --- | --- | --- |
| **Reported incidents** | | | | | |
|  | EU |  |  |  |  |
| WW |  |  |  |  |
|  | EU |  |  |  |  |
| WW |  |  |  |  |
| **Non-serious incident – Known undesirable side-effects** | | | | | |
|  | EU |  |  |  |  |
| WW |  |  |  |  |
|  | EU |  |  |  |  |
| WW |  |  |  |  |

Table 51: Type of patient problem

| **Type of root-cause** | **Region** | **YYYY** | **YYYY** | **YYYY** | **YYYY** |
| --- | --- | --- | --- | --- | --- |
| **Reported incidents** | | | | | |
|  | EU |  |  |  |  |
| WW |  |  |  |  |
|  | EU |  |  |  |  |
| WW |  |  |  |  |
| **Non-serious incident – Known undesirable side-effects** | | | | | |
|  | EU |  |  |  |  |
| WW |  |  |  |  |
|  | EU |  |  |  |  |
| WW |  |  |  |  |

[Manufacturer short name] has also conducted X CAPA related to the device as indicated in the following table.

Table 53: Summary of CAPA

| **Type of action** | **Initiation date** | **Scope of the CAPA** | **Status of the CAPA** | **Manufacturer Reference Number** | **CAPA description** | **Root cause** | **Effectiveness of the CAPA if closed** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| CA | XX/MM/YYYY |  | *[in process, finalized]* |  |  | **DXXXX *[code]***  **WWWW *[terms]*** | *[Effectiveness verified, CAPA in progress]* |
| PA |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

[Manufacturer short name] has also conducted X Field Safety Corrective Action (FSCA) as indicated in the following table.

Table 52: Summary of Field Safety Corrective actions

| **Type of action** | **Issuing date** | **Scope of the FSCA** | **Status of the FSCA** | **Manufacturer Reference Number** | **Rationale and description of action taken** | **Impacted Regions** |
| --- | --- | --- | --- | --- | --- | --- |
| *[Recall, FSN,…]* | XX/MM/YYYY |  | *[in process, finalized]* |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

### Conclusion of clinical data available and appraisal

The different sources of clinical data have been consulted and resulted in the identification of clinical data applicable to [Device short name] and its equivalent device, to support the device safety and performance.

All clinical data available to support the DUE compliance to applicable GSPRs have been appraised as summarized in the following table.

Table 54: Appraisal summary of clinical data

| **Reference** | **Clinical data** | **Appraisal** | | | |
| --- | --- | --- | --- | --- | --- |
| **Contribution** | **Suitability** | **LoE** | **Rank** |
| **Clinical investigation** | | | | | |
| CI1 |  |  |  |  |  |
| CI2 |  |  |  |  |  |
| **PMCF activities** | | | | | |
| PMCF1 |  |  |  |  |  |
| PMCF2 |  |  |  |  |  |
| **Literature** | | | | | |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| **Vigilance and recall in publicly available database** | | | | | |
| - | Data presented in **Section 3.3.4** | N/A | N/A | N/A | 7 |
| **PMS data generated and held by the manufacturer** | | | | | |
| - | Data presented in **Section 3.3.5** | N/A | N/A | N/A | 7 |
| **Preclinical data** | | | | | |
| - | Preclinical Data presented in **Section 3.3.1** | N/A | N/A | N/A |  |

The data summarized and appraised in **Section 3.3** are analyzed in **Section 3.4** to justify the sufficient level of clinical data available to support the compliance to the applicable GSPR.

## Clinical data analysis

### Level of clinical evidence available

The level of clinical data required has been determined in **Section 3.2**. As described in the following table, the minimum level of clinical data required to support the compliance to relevant GSPRs is achieved for all critical device characteristics and all critical characteristics of the intended use.

The device/intended use characteristics in the table below shall include all critical characteristics identified in **Section 1.5**; (e.g., the intended use shall include all sub-indications in which the device is claimed to be used).

Table 55: Level of clinical data available

| **Intended use**  **Device Characteristics** | | **Indication 1** | **Indication 2** | **Indication 3** |
| --- | --- | --- | --- | --- |
| **Design** |  | * Rank 12 (Section X) * Rank 7 (Section X): XXX devices sold and 0.0001% of complaints 0% reported to CA * Rank 3 (Section X): Y CI, Y articles with n=XXX from Z to Z |  |  |
|  |  |  |  |
| **Type** |  |  |  |  |
| **Version** |  |  |  |  |
| **Size** |  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

For all weaknesses/gaps identified, describe the PMCF activities planned/ongoing to cover the problem.

### Safety evaluation (GSPR 1,2,3)

[Device short name] shall be designed and manufactured in way that does not compromise the clinical condition and the safety of patients and intended users. The clinical evaluation has identified the possible risks during normal conditions of use with the purpose to confirm the suitability of risk estimation and the risks are mitigated as far as possible using the principles described in EN ISO 14971:2019+A11:2021. In addition, the review of resulting residual risks will confirm the suitability of labeling. The following table summarizes the results of this review for all risks identified during the clinical evaluation.

Table 56: Adequacy of clinical data with IFU and risk management file

| **Clinical risks (including side-effects)** | **Risk Management File** | **Instruction for use** |
| --- | --- | --- |
| **Document of reference: See section 1.11** | **Document of reference: see section 1.11** |
| ***From SoA (including similar devices)*** Remove for devices with a long history of use | | |
|  | “XXX” Refer to the risk and risk estimation  The risk has been mitigated AFAP as indicated | “Xxxxxxxx” Refer to the IFU statement covering the risk |
|  |  |  |
|  |  |  |
|  |  |  |
| ***From Equivalent device***Remove if not applicable | | |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| ***From Device under evaluation*** | | |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

As described in **Section 3.3.5,** no trends have been identified exceeding the threshold values defined in the risk analysis for the non-significant incidents or known undesirable side-effects. Alternatively, describe the trends exceeding the threshold value, the associated CAPA and the conclusion on the B/R profile.

All serious risks[[1]](#footnote-2) identified during the clinical use of the device are evaluated for acceptability against the acceptance criteria defined based on the current knowledge and state of the art (including similar devices). The acceptability of risks is described in **Section 3.4.3**.

All risks identified though the clinical evaluation have been evaluated and mitigated as far as possible and are compatible with a high level of protection of health and safety. The labeling has also been reviewed and is aligned with the risks identified during the clinical evaluation.

### Acceptability of clinical risks and side-effects (GSPR 1,8)

A systematic search of clinical data (See **Section 3.3**) for the period from DD/MM/YYYY to DD/MM/YYYY raised a list of clinical risks for the use of [Device short name] or equivalent device. The following table gathers the clinical risks identified for the use of the subject or equivalent device with the corresponding rates, when available.

A systematic search of clinical data on similar devices (see **Section 2.2**) for the period from DD/MM/YYYY to DD/MM/YYYY allowed the identification of acceptance criteria for the recognized clinical risks established in the SoA.

The following table compares the quantitative data resulting from the use of [Device short name] or equivalent device to the acceptance criteria defined based on the SoA.

Table 57: Acceptability of clinical risks

| **Clinical risks on [Device short name]** | **State of the Art rates** | **Reported rates for [device short name]** | **Acceptability and rationale** |
| --- | --- | --- | --- |
|  | From X to X | Clinical investigation:  From X to X | Yes/No |
| Clinical literature: From X to X |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

A tabular format is recommended but all clinical risks can be presented in sub-sections;

When clinical risks do not meet the acceptance criteria, a justification shall be indicated based on (for instance):

* Isolated case
* Significance of the risks
* Other recognized risks that are not reported for the subject device
* Discrepancy of results
* Benefits of the device
* Other

PMCF may be required for the risks that do not meet the acceptance criteria with a non-sufficiently strong rationale. Though the benefits of using the device may outweigh those risks, specific monitoring shall be implemented.

In conclusion, all clinical risks identified for the use of [Device short name] or the equivalent device, including all known undesirable side-effects have been evaluated meeting the acceptance criteria taking into account the current knowledge and state of the art.

### Performance evaluation (GSPR 1,6)

Based on the pre-clinical data presented in **Section 3.3.1**, [Manufacturer short name] demonstrated [Device short name] has been designed, manufactured, labelled and packaged according to the current state of the art, meeting the applicable requirements of European harmonized, international or technical standards and Common Specifications (CS) recognized in Europe for the generic device type.

The performance of the [Device short name] has been evaluated through the review of cumulative evidence for the outcome parameters (i.e., endpoints) that support the performance and safety claims as compared to the acceptance criteria defined based on the SoA (See **Section 2.2.1.3**).

The acceptance criteria for the key safety and performance outcome parameters were within the acceptance criteria, except for the following for which the gap has been evaluated clinically non-significant:

* XXX (justify the gaps)

In addition, [Manufacturer short name] considered the minimum level of clinical data required as determined in **Section 3.2** has been achieved for all the clinical claims available in the labelling or marketing materials for the indication and population treated/diagnosed with the device.

The following table summarizes the clinical data available for the safety and performance allegations claimed by [Manufacturer short name].

Table 58: Substantiation of clinical claims

| **Claims** | **Type of claims** | **Outcome parameters** | **Results** | | **Acceptable** |
| --- | --- | --- | --- | --- | --- |
| **Clinical data available** | **Rank** |
| **Performance** | | | | | |
|  | Clinical / Non-Clinical |  | Clinical investigation: include the result (if comparative data required, include the p value), include the number of patients and source |  |  |
| PMCF: include the result (if comparative data required, include the p value), include the number of patients and source |  |
| Literature: include the result (if comparative data required, include the p value), include the number of patients and source |  |
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| **Safety** | | | | | |
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Note: the general S&P claims shall be substantiated for the complete indication or for all types of targeted patients; an additional column may be integrated for that purpose if necessary.

### Benefit / risk profile (GSPR 8)

The description of B/R profile should be sufficient on its own. Information from other sections can be repeated here.

[Device short name] is a class X device according to Annex VIII of the MDR.

[Device short name] is XXX include a short device description.

[Device short name] is indicated for XXX indicate the exact indication for use statement.

A systematic search of clinical data has been conducted and relevant safety and performance data on [Device short name] and equivalent device, have been found:

* X clinical investigations on the subject device or equivalent device (see **Section 3.3.1**)
* X literature articles on the subject device or equivalent device (see **Section 3.3.3**)
* X PMCF specific procedures on the subject device or equivalent device, under the form of [Registry, PMCF investigation, PMCF user survey, etc;] (see **Section 3.3.2**)
* PMS data generated and held by [Manufacture short name] (see **Section 3.3.5**)and PMS data from external publicly available database (see **Section 3.3.4**).

As discussed in **Section 3.4.1** and using the criteria defined in Appendix III of the MDCG 2020-6, [Manufacturer short name] evaluated a sufficient level of clinical evidence has been reached to demonstrate the safety and performance of [Device short name] for its intended use and support the compliance to relevant GSPRs. Highlight the need of PMCF if the level of clinical data is not reached for a specific indication/population/device in the range.

**Safety**

XXX number of devices sold/uses [Device short name] have been sold/used from DD/MM/YYYY to DD/MM/YYYY. For the same period, the corresponding PMS data generated and held [Manufacture short name] for [Device short name] showed an overall complaint rate of XX% and YY% of incidents reported to the regulatory authorities. Please customized if the CER includes different type of devices (e.g., implants and accessories) as the PMS data must be presented per type of products.

The trend analysis conducted according to Article 88 of the MDR did not show any significant increase in trends and any increase in likelihood or severity of risks as compared to the threshold values defined in the risk management documents. Please identify any increased trend and how the trend has been justified and if necessary, the CAPA defined, impact on B/R profile and if they have been reported to the authorities.

**Section 3.4.2** justified that all risks identified in the clinical data for [Device short name] and its equivalent device have been assessed, evaluated and mitigated as far as possible according to the principles described in EN ISO 14971:2019+A11:2021. In addition, **Section 3.4.3** demonstrated that all clinical risks identified in the clinical data for [Device short name], including all known undesirable side-effects, have been accepted when weighted against the acceptance criteria determined based on the state of the art. A thorough review has been performed and documented in **Section 3.4.2** confirming the Instructions for use are adequate and consistent with the clinical data and risk management documents.

Highlight any specific concerns related to clinical risks with the appropriate justification. Highlight the need of PMCF if required.

[Manufacture short name] also defined safety claims that have been substantiated by a sufficient level of clinical data as described in **Section 3.4.4.**

**Performance**

Based on the pre-clinical data presented in **Section 3.3.1,** [Manufacture short name] demonstrated [Device short name] has been designed, manufactured, labelled and packaged according to the current state of the art, meeting the applicable requirements of European harmonized, international or technical standards and Common Specifications (CS) recognized in Europe for the generic device type.

**Section 3.4.4** also demonstrated that all performances claimed by [Manufacture short name] met the acceptance criteria defined based on the state of the art and have been substantiated by a sufficient level of clinical data.

Highlight any specific concerns related to clinical performance with the appropriate justification. Highlight the need of PMCF if required.

Those claims also led to clinical benefits for patients as delineated in the following table. The benefits for the use of [Device short name] are acceptable regarding the acceptance criteria defined based on the state of the art.

Table 59: Substantiation of clinical benefits

| **Clinical Benefits** | **Type of claims** | **Outcome parameters and specifications** | **Results** | | **Acceptable** |
| --- | --- | --- | --- | --- | --- |
| **Clinical data available** | **Rank** |
|  | Clinical / Non-Clinical |  | Clinical investigation: include the result (if comparative data required, include the p value), include the number of patients and source |  |  |
| PMCF: include the result (if comparative data required, include the p value), include the number of patients and source |  |  |
| Literature: include the result (if comparative data required, include the p value), include the number of patients and source |  |  |
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Note: when necessary, a supplemental column shall be added to provide the evidence of benefits per indication or target population. Alternatively, the table can be duplicated.

Major clinical data (optional)

XXXX Overview and results of CI, pivotal articles on DUE that support the benefits

Comparative data in the literature (optional)

XXXX Present all controlled/comparative data to highlight specific clinical data on DUE in comparison to other alternatives/devices (to show the equivalence or superiority). This section can be removed if no comparative data are available.

Discussion of B/R concerns

No concern or remaining questions are left regarding the clinical data available that support the compliance of [Device short name] with the applicable GSPRs.

/OR

XXXX When S&P concerns have been raised in the CER without sufficient justification, that section shall weigh how the concerns do not affect the B/R ratio in comparison to the SoA. PMCF is generally recommended for confirmation.

Conclusion

In conclusion, the clinical data available confirm that the risks are acceptable when weighed against the intended benefits and are compatible with a high level of protection of health and safety taking into account the current knowledge and state of the art.

# Conclusion

In respect of the requirements in 2017/745 (MDR), the clinical evidence support the safety and effectiveness of the [Device Short Name], and especially:

1. Benefit/risk ratio is acceptable taking into account the current knowledge and state of the art of the medical condition treated by [Device Short Name]
2. Undesirable side-effects and clinical risks are acceptable taking into account the current knowledge and state of the art of therapeutic alternatives
3. The information materials supplied by the [Manufacturer Short Name], as well as the intended purpose and risk reduction measures are adequate.
4. The claims foreseen by [Manufacturer Short Name] are adequate.
5. The clinical data, the information materials supplied by the manufacturer, the risk management documentation for the device under evaluation are consistent together and with the current knowledge and state of the art.
6. The device under evaluation, including the IFU, is suitable to the intended users taking into account the usability of the device
7. The PMS / PMCF plan in regard to the device is appropriate.

The clinical data available confirm that the risks are acceptable when weighed against the intended benefits and are compatible with a high level of protection of health and safety taking into account the current knowledge and state of the art. In conclusion, the clinical data support the conformity of [device short name] with GSPR 1, X, X, X and 8.

However, in addition to the PMS activities (including PMCF general procedures), a PMCF specific procedure has been planned for the following objectives:

* XXX describe the objective as defined in Annex XIV Part B and a justification of the gaps/weaknesses identified (e.g., CER based on the equivalence, no data until the entire lifetime)

The following residual risks also need to be addressedthrough a specific PMCF procedure /or monitored during the PM*S*:

* XXX describe the objective as defined in Annex XIV Part B and a justification of the gaps/weaknesses identified (e.g., confirm the device safety)

/OR XXX include a rationale if no PMCF specific procedures is required

In conclusion, [Manufacturer Short Name] considers GSPR 1, X, X, X and 8 of the MDR are met for the [Device Short Name] regarding the clinical evidence available.

The CER will be issued every XX years consistently with the issuance of PSUR/PMS report and PMCF Evaluation Report Use same frequency as PMS/PMCF.

# Reference

1. Author, Author. Title. Journal. REF (e.g., Month DD YYYY; N°:page-page). doi:
2. Author, Author. Title. Journal. REF (e.g., Month DD YYYY; N°:page-page). doi:

Full articles are included in **Appendix J - Articles**

# Appendix A – Evaluator qualifications and declaration of interest

Copy/insert CV and declaration of interest

# Appendix B – Appraisal criteria

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# Appendix C – Clinical / PMCF investigation protocols and reports

The following clinical / PMCF investigation protocols and reports have been issued with [device short name]

Table 60: CI/PMCF protocols and report for [Device short name]

| **Reference** | **Title** | **Protocol** | **Report** |
| --- | --- | --- | --- |
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# Appendix D – Clinical data search protocol

The following table is the history of clinical data search protocol implemented for [Device short name].

Table 61: Clinical data search protocol for [Device short name]

| **Reference** | **Objective** | **Period covered** |
| --- | --- | --- |
| XXXXX-PRO rev.1 | 1 – SoA | From DD/MM/YYYY to DD/MM/YYYY |
| 2 – S&P AC | From DD/MM/YYYY to DD/MM/YYYY |
| 3 – S&P | From DD/MM/YYYY to DD/MM/YYYY |

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# Appendix E – Literature search report for SoA

The following table is the correspondence between clinical data search protocol and literature search reports implemented for SoA.

Table 62: Literature search report for SoA

| Clinical Data Search Protocol | Literature Search Report | | |
| --- | --- | --- | --- |
| Reference | **Objective** | Reference | Period covered |
| XXXXX-PRO rev.1 | 1 – SoA | XXXXX-RE-001 rev.1 | From DD/MM/YYYY to DD/MM/YYYY |
| XXXXX-RE-002 rev.1 | From DD/MM/YYYY to DD/MM/YYYY |
| XXXXX-RE-003 rev.1 | From DD/MM/YYYY to DD/MM/YYYY |

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# Appendix F – Literature search report for acceptance criteria

The following table is the correspondence between clinical data search protocol and literature search reports implemented for the definition of acceptance criteria of S&P.

Table 63: Literature search report for AC

| Clinical Data Search Protocol | Literature Search Report | | |
| --- | --- | --- | --- |
| Reference | **Objective** | Reference | Period covered |
| XXXXX-PRO rev.1 | 2 – S&P AC | XXXXX-RE-001 rev.1 | From DD/MM/YYYY to DD/MM/YYYY |
| XXXXX-RE-002 rev.1 | From DD/MM/YYYY to DD/MM/YYYY |
| XXXXX-RE-003 rev.1 | From DD/MM/YYYY to DD/MM/YYYY |

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# Appendix G – Literature search report for S&P

The following table is the correspondence between clinical data search protocol and literature search reports implemented for the S&P of [device short name].

Table 64: Literature search report for S&P

| Clinical Data Search Protocol | Literature Search Report | | |
| --- | --- | --- | --- |
| Reference | **Objective** | Reference | Period covered |
| XXXXX-PRO rev.1 | 3 – S&P | XXXXX-RE-001 rev.1 | From DD/MM/YYYY to DD/MM/YYYY |
| XXXXX-RE-002 rev.1 | From DD/MM/YYYY to DD/MM/YYYY |
| XXXXX-RE-003 rev.1 | From DD/MM/YYYY to DD/MM/YYYY |

Use Lex form: LEX-FORM-EU-005

# Appendix H – Vigilance/recall search report

The following table is the correspondence between clinical data search protocol and vigilance/recall search reports.

Table 65: Vigilance/recall search reports

| Clinical Data Search Protocol | Vigilance/Recall Search Report | | |
| --- | --- | --- | --- |
| Reference | **Objective** | Reference | Period covered |
| XXXXX-PRO rev.1 | 1 – S&P AC  3 – S&P | XXXXX-RE-001 rev.1 | From DD/MM/YYYY to DD/MM/YYYY |
| XXXXX-RE-002 rev.1 | From DD/MM/YYYY to DD/MM/YYYY |
| XXXXX-RE-003 rev.1 | From DD/MM/YYYY to DD/MM/YYYY |

Use Lex form: LEX-FORM-EU-008

# Appendix I – Existing literature and gap search report

The following table is the correspondence between clinical data search protocol, existing literature search report(s) and new literature search report(s).

Table 66: Existing and gap search reports

| Clinical Data Search Protocol | Existing Literature Search considered | | New Literature search reports and gap searches | |
| --- | --- | --- | --- | --- |
| Reference | Reference | Period covered | Reference | Period covered |
| XXXXX-PRO rev.1 | XXX |  | XXXXX-RE-001 rev.1 |  |
| XXX |  |
| XXX |  | XXXXX-RE-002 rev.1 |  |
| XXX |  |

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# Appendix J - Articles

1. Serious shall be understood as risks meeting the reporting criteria in EU. All non-reportable risks being monitored via trend analysis. [↑](#footnote-ref-2)