**Summary of Safety and Clinical Performance**

For

[Device Name]

Manufacturer Name: [Manufacturer name]

Document Number: XXXX

Revision: XXXX

# Summary of Safety and Clinical Performance (SSCP) for Healthcare Professionals

This SSCP is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions for Use (IFU) as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for user/healthcare professionals. Following this information, there is a summary intended for patients.

Manufacturer’s reference number for the SSCP: XXXX rev.X

# Device identification and general information

## Device trade name(s)

|  |  |
| --- | --- |
| **Device Trade Name(s) in Europe:** |  |

## Manufacturer’s name and address

|  |  |
| --- | --- |
| **Manufacturer’s Name:** |  |
| **Manufacturer’s Address:** |  |

## Manufacturer’s single registration number (SRN)

|  |  |
| --- | --- |
| **Manufacturer’s SRN:** |  |

## Basic unique device identification-device identifier (UDI-DI)

|  |  |
| --- | --- |
| **Basic UDI-DI:** |  |

OR If the device is a system

|  |  |  |
| --- | --- | --- |
| **Basic UDI-DI of the system:** |  | |
| **Basic UDI-DI of devices in the system:** | |  |

## Medical device nomenclature description/text

|  |  |  |  |
| --- | --- | --- | --- |
| **EMDN Code:** |  | **EMDN Description:** |  |

OR When bundling of devices is relevant in the same SSCP:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Basic UDI-DI:** |  | **EMDN Code:** |  | **EMDN Description:** |  |

## Class of device

|  |  |
| --- | --- |
| **Device Classification:** | **Rule (MDR Annex VIII):** |

OR When bundling of devices is relevant in the same SSCP:

|  |  |  |  |
| --- | --- | --- | --- |
| **Basic UDI-DI:** |  | **Device Classification:** |  |

## Year when the first Conformité Européenne (CE)certificate was issued covering the device(s)

|  |  |
| --- | --- |
| **Year of First CE Marking Under 93/42/EEC OR 90/385/EEC:** |  |
| **Year of First CE Marking Under (EU) 2017/745:** |  |

OR When bundling of devices is relevant in the same SSCP:

|  |  |  |
| --- | --- | --- |
| **Basic UDI-DI:** | **Year of First CE Marking Under 93/42/EEC OR 90/385/EEC:** | **Year of First CE Marking Under (EU) 2017/745:** |
|  |  |  |

## Authorized representative: name and single registration number

N/A - [Manufacturer Name] is located in Europe.

OR

|  |  |
| --- | --- |
| **Authorized Representative Name:** |  |
| **Authorized Representative Address:** |  |
| **Authorized Representative SRN:** |  |

## Notified Body’s (NB) name and single identification number

|  |  |
| --- | --- |
| **Notified Body’s Name:** |  |
| **Notified Body’s Single Identification Number:** |  |

# Intended use of the device(s)

## Intended purpose

As specified in the IFU

## Indications(s) and target population(s)

### Indication(s)

As specified in the IFU

### Target population(s)

As specified in the IFU

## Contraindications and/or limitations

### Contraindications

As specified in the IFU

### Limitations

As specified in the IFU

# Device description

## Description of the device(s)

The device description in the SSCP needs to include all the device(s)/device system associated with the same Basic UDI-DI. The description of the device(s)/device system should be comprehensive and can be presented in different ways to include, if such exist, any configurations / combinations / different sizes / specifications of any software versions that can be related to safety and/or performance and their release dates / etc. The description should also include any model number or similar designation used to identify the device(s)/device system.

Include the device description as specified in the CER and ensure that the following elements are addressed:

* Picture(s) of the device
* Operating principles and mode(s) of action
* Design characteristics, for example key functional elements
* Any materials or substances in contact with the patient’s tissues
* Information on whether the device is for single use and its method of sterilization
* For absorbable implants: stability retention profile, including time to loss of stability and the absorption time
* Information whether or not the device includes a medicinal substance, tissues, or cells from human or animal origin (or their derivatives), substances absorbed by or locally dispersed in the human body, carcinogenic, mutagenic, or toxic to reproduction (CMR), endocrine-disrupting substances, or materials that could result in sensitization or an allergic reaction by the patient or user

## Previous generations or variants

[Device name] does not have previous generations and is not composed of variants.

OR

| **Name** | **Description** | **Date of Implementation** | **Reason for the Change** |
| --- | --- | --- | --- |
| ***Variants*** | | | |
|  |  |  |  |
| ***Previous Generations*** | | | |
|  |  |  |  |

## Accessories intended to be used in combination with the device

[Device name] is not intended to be used with accessories.

OR

[Device name] is intended to be used with the following accessories as defined in MDR Article 2(2):

| **Basic UDI-DI** | **Device trade name** | **Description** |
| --- | --- | --- |
|  |  |  |

## Devices and products intended to be used in combination with the device(s)

[Device name] is not intended to be used with medical devices or products (other than those in scope of the SSCP or described in **Section 3.3**).

OR to be removed if not applicable

[Device name] is intended to be used with the following medical devices not in scope of the SSCP.

| **Basic UDI-DI** | **Device trade name** |
| --- | --- |
|  |  |

OR to be removed if not applicable

[Device name] is intended to be used with the following products (other than those in scope of the SSCP or described in **Section 3.3**)**.**

| **Product trade name** |
| --- |
|  |

# Risks and warnings

## Residual risks and undesirable effects

Residual risks and undesirable effects are referred to as clinical risks in the SSCP and are patient-specific risks (e.g., undesirable side-effects, injury due to malfunctions).

The following tabledescribes the clinical risks and corresponding rates for the use of [Device name]. They are sourced from the clinical data available on the device, including:

* [Manufacturer Name]’s sponsored clinical investigation (CI) and PMCF study/studies
* Clinical literature on [Device name] or its equivalent device
* Post-market surveillance (PMS) data, including complaints and vigilance (rate estimated based on the total number of sales/uses)*.*

Any serious incident that has occurred in relation to the device(s) should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. Hence, the estimated rates are based on spontaneously reported incidents or serious incidents that are under-reported.

To be customized as needed

| **Clinical Risks** | **Timepoint** | **Quantitative Data** | | |
| --- | --- | --- | --- | --- |
| **CI/PMCF** | **Literature** | **PMS** |
| Include the list of clinical risks (i.e., patient-related) as specified in the IFU (e.g., complications) |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

Always indicate the quantitative data in relation to the time.

## Warnings and precautions

As specified in the IFU

## Summary of field safety corrective actions (FSCA), including field safety notice (FSN)

No FSCA has been conducted for [Device name] from DD/MM/YYYY to DD/MM/YYYY.

OR

The following table presents the FSCA conducted with [Device name] from DD/MM/YYYY to DD/MM/YYYY.

| **FSCA Identifier and Short Description** | **Date of Implementation** | **Status** | **Circumstances** | **Actions Undertaken** |
| --- | --- | --- | --- | --- |
|  | DD/MM/YYYY | Ongoing/ closed |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

# Summary of clinical evaluation and post-market clinical follow-up

## Summary of clinical data related to equivalent device

No device has been claimed and justified as equivalent to [Device Name].

OR

Conformity of [Device name] was assessed and endorsed by [NB Name] (XXXX NB 4-digit) on the basis of equivalence with the following devices:

| **Equivalent Device Name** | **Basic UDI-DI** | **Manufacturer Name** | **Related SSCP** |
| --- | --- | --- | --- |
|  |  |  | Not available in European Database on Medical Devices (EUDAMED)  OR  Available in EUDAMED  *+hyperlink to the SSCP* |

If the data are not available in EUDAMED, complete the following subsections. If the data are available in EUDAMED, remove the following subsections.

The following subsections provide the detail of clinical data available for the equivalent device.

### Summary of clinical data from conducted investigations of the equivalent device(s) before the CE marking

Follow the template text from section 5.2**.**

### Summary of clinical data of the equivalent device(s) from other sources

Follow the template text from section 5.3**.**

## Summary of clinical data from conducted investigation of the device(s) before the CE-marking

The following table(s) presents the premarket clinical investigations conducted for [Device Name].

| **Identity of the investigation/study:** | 1. Indicate the Title | | |
| --- | --- | --- | --- |
| **Geography area:** |  | | |
| **Source:** |  | | |
| **Identity of the device:** |  | | |
| **Intended use of the device:** |  | | |
|  |  | | |
| **Objectives:** |  | | |
| **Study design:** |  | **Follow-up:** |  |
| **Primary endpoint(s):** |  | | |
| **Secondary endpoint(s):** |  | | |
| **Inclusion criteria:** |  | **Exclusion criteria:** |  |
| **Summary of method:** |  | | |
|  | | | |
| **Number of enrolled patients:** |  | | |
| **Study population:** |  | | |
|  | | | |
| **Summary of results:** |  | | |
| * **Performance endpoint(s)** | |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Performance endpoints*** | | | |  |  |  | |  |  |  | | | |
| * **Safety endpoint(s)** | |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Safety endpoints*** | | | |  |  |  | |  |  |  | | | |
| * **Adverse events and side-effects** | |  |  |  | | --- | --- | --- | | **Events** | **Number** | **Rate** | |  |  |  | | | |
|  | | | |
| **Status:** |  | | |
| **Limitations:** |  | | |
| **Deficiency:** |  | | |

## Summary of clinical data from other sources

### Literature articles

A systematic literature review was implemented and yielded XX articles[indicate the article number]in which [Device Name] was used. The articles included # patients aged from X to Y years with follow-up ranging from X to Y years.

The citations of literature articles are described in **Section 8**. **Section 5.4.1** summarizes the literature results for the key safety and performance outcomes relevant to support the compliance to General Safety and Performance Requirements (GSPR) of [Device Name].

### Post-market clinical follow-up (PMCF) investigation and/or registry

The following table(s) present the PMCF investigations and/or registry conducted for [Device Name].

| **Identity of the investigation/study:** | 1. Indicate the Title | | |
| --- | --- | --- | --- |
| **Type:** | PMCF investigation/registry | | |
| **Geography area:** |  | | |
| **Source:** |  | | |
| **Identity of the device:** |  | | |
| **Intended use of the device:** |  | | |
|  |  | | |
| **Objectives:** |  | | |
| **Study design:** |  | **Follow-up:** |  |
| **Primary endpoint(s):** |  | | |
| **Secondary endpoint(s):** |  | | |
| **Inclusion criteria:** |  | **Exclusion criteria:** |  |
| **Summary of method:** |  | | |
|  | | | |
| **Number of enrolled patients:** |  | | |
| **Study population:** |  | | |
|  | | | |
| **Summary of results:** |  | | |
| * **Performance endpoint(s)** | |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Performance endpoints*** | | | |  |  |  | |  |  |  | | | |
| * **Safety endpoint(s)** | |  |  |  | | --- | --- | --- | | **Endpoints** | **Timepoints** | **Results** | | ***Safety endpoints*** | | | |  |  |  | |  |  |  | | | |
| * **Adverse events and side-effects** | |  |  |  | | --- | --- | --- | | **Events** | **Number** | **Rate** | |  |  |  | | | |
|  | | | |
| **Status:** |  | | |
| **Limitations:** |  | | |
| **Deficiency:** |  | | |

### Post-market surveillance (PMS) data

The review of PMS data available did not identify any new or change in likelihood or severity of serious incidents, or any trend or significant increase in the frequency or severity of non-serious incidents and known undesirable side-effects.

Alternatively, describe the new risks identified or trends that affected the B/R profile.

## Overall summary of the clinical performance and safety

### Assessment of clinical benefits, performance and safety

The following table describes the clinical benefits of [device name].

| **Clinical Benefits Claimed** | **Endpoints** | **Clinical Evidence** | |
| --- | --- | --- | --- |
| **Clinical investigation, PMCF and Registry** | **Literature Article** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

The following table describes the performance claims for [device name].

| **Performance claims** | **Endpoints** | **Clinical Evidence** | |
| --- | --- | --- | --- |
| **Clinical investigation, PMCF and Registry** | **Literature Article** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

The following table describes the safety claims for [device name].

| **Safety claims** | **Endpoints** | **Clinical Evidence** | |
| --- | --- | --- | --- |
| **Clinical investigation, PMCF and Registry** | **Literature Article** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

### Benefit-risk assessment

#### Evaluation of undesirable side-effects

All clinical risks, including undesirable side-effects have been identified in **Section 4.1**. The Incidence rates are aligned with the state of the art (SoA) and considered acceptable.

#### Benefit-risk profile

The Benefit-Risk profile of [device name] has been evaluated for the indication described in **Section 2.2.1.**

XXXX Include a summary of B/R profile based on the CER for each indication/target population, as necessary.

In conclusion, the clinical data available confirmed 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 SoA.

### Ongoing or planned post-market clinical follow-up

The following table describes the ongoing/planned PMCF activities for [device name].

| **PMCF Activity** | **Short Description** | **Objectives** | **Status** | **Rationale and Known Limitations of the PMCF Activity** |
| --- | --- | --- | --- | --- |
| User survey / patient survey / registry / PMCF investigation |  | Select those relevant consistently with the PMCF plan:   * Confirming the safety and performance of the device throughout its expected lifetime, * Identifying previously unknown side-effects and monitoring the identified side-effects and contraindications, * Identifying and analyzing emergent risks on the basis of factual evidence, * Ensuring the continued acceptability of the benefit-risk ratio * Identifying possible systematic misuse or off-label use of the device, with a view to verifying that the intended purpose is correct. | Ongoing/planned for/ updated yearly | Rationale:  Limitations: |

The Section C of the PMCF plan (as defined in the Medical Device Coordination Group [MDCG 2020-7]) can be copied to replace the table above.

# Possible diagnostic or therapeutic alternatives

The following table lists and describes the therapeutic alternatives for the treatment/diagnosis of the medical condition(s) for which [device name] is intended to be used.

| **Treatment/Diagnostic Options** | **Description** | **Benefits** | **Risks** |
| --- | --- | --- | --- |
| XXX (targeted treatment/diagnostic option) |  |  |  |
| XXX (alternative treatment/diagnostic option) |  |  |  |
| XXX (alternative treatment/diagnostic option) |  |  |  |
| XXX (alternative treatment/diagnostic option) |  |  |  |

# Suggested profile and training for users

Indicate the required user qualifications or trainings as specified in the IFU

# Reference to harmonized standards and common specifications (CS) applied

| **Harmonized Standards, Common specifications or Adopted Monographs** | **Titles** |
| --- | --- |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

# Revision history

| **SSCP Revision Number** | **Date Issued** | **Change Description** | **Revision Validated by the Notified Body** |
| --- | --- | --- | --- |
| 1 |  |  | ☐ Yes  Validation language:  ☐ No |

# References

Include the references to articles discussed in the healthcare professional section of the SSCP

# Summary of Safety and Clinical Performance (SSCP) for Patients

Language: English

Document revision: XXX rev.X

Date issued: DD/MM/YYYY

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

The SSCP is not intended to give general advice on the treatment/diagnosis of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation.

This SSCP is not intended to replace an Implant Card or the Instructions for Use to provide information on the safe use of the device.

# Device identification and general information

## Device trade name

|  |  |
| --- | --- |
| **Device Trade Name(s) in Europe:** |  |

## Manufacturer’s name and address

|  |  |
| --- | --- |
| **Manufacturer’s Name:** |  |
| **Manufacturer’s Address:** |  |

## Basic unique device identification-device identifier (UDI-DI)

|  |  |
| --- | --- |
| **Basic UDI-DI:** |  |

OR If the device is a system

|  |  |  |
| --- | --- | --- |
| **Basic UDI-DI of the system:** |  | |
| **Basic UDI-DI of devices in the system:** | |  |

## Year when the device was first CE-marked

|  |  |
| --- | --- |
| **Year of First CE Marking Under 93/42/EEC OR 90/385/EEC:** |  |
| **Year of First CE Marking Under (EU) 2017/745:** |  |

OR When bundling of devices is relevant in the same SSCP:

|  |  |  |
| --- | --- | --- |
| **Basic UDI-DI:** | **Year of First CE Marking Under 93/42/EEC OR 90/385/EEC:** | **Year of First CE Marking Under (EU) 2017/745:** |
|  |  |  |

# Intended use of the device

## Intended purpose

Specify the information sourced from the IFU in terms understandable by a layman

## Indications and intended patient groups

### Indications

Specify the information sourced from the IFU in terms understandable by a layman

### Intended patient groups

Specify the information sourced from the IFU in terms understandable by a layman

### Contraindications

Specify the information sourced from the IFU in terms understandable by a layman

# Device description

## Device description and material/substances in contact with patient tissues

Specify the information (including dimensions, relevant images/figures, device lifetime, and implant duration inside the body for implantable devices, materials/substances in contact with patients) to be understandable by a layman.

## Information about medicinal substances in the device

There is no medicinal substance in [device name].

OR

[Device name] contains the following medicinal substances:

* Medicinal substance #1
* Medicinal substance #2

## Description of how the device is achieving its intended mode of action

Specify the information in terms understandable by a layman.

## Description of accessories

[Device name] is not intended to be used with accessories.

OR

[Device name] is intended to be used with the following accessories:

| **Device trade name** | **Description** |
| --- | --- |
|  |  |

# Risks and warnings

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

## How potential risks have been controlled or managed

[Manufacturer name] continuously monitors, identifies, and analyses risks related to the [Device name] as part of a documented risk management process.

The risks associated with the use of the [Device name] are mitigated as far as possible via design or manufacturing solutions and the effectiveness of solutions is verified by testing. The IFU states the remaining risks as side-effects or through contraindications, warnings and precautions.

## Remaining risks and undesirable effects

Remaining risks and undesirable effects are named clinical risks in the SSCP and are understood as any patient-specific risks (e.g., complications).

The following clinical risks have been identified following the use of [device name]:

| **Clinical Risks** | **Timepoint** | **Rate** |
| --- | --- | --- |
| Include the clinical risks as specified in the IFU (e.g., complications) using terms understandable by a layman. |  |  |

## Warnings and precautions

Include warnings/precautions from the IFU that are relevant for the patients and in terms understandable by a layman.

## Summary of field safety corrective action (FSCA) including field safety notice (FSN)

No FSCA has been conducted for [Device Name] from DD/MM/YYYY to DD/MM/YYYY.

OR

The following table presents the field safety corrective actions conducted with [Device Name] from DD/MM/YYYY to DD/MM/YYYY.

| **FSCA Identifier and Short Description** | **Date of Implementation** | **Status** | **Circumstances** | **Actions Undertaken** |
| --- | --- | --- | --- | --- |
|  | DD/MM/YYYY | Ongoing/ closed |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

# Summary of clinical evaluation and post-market clinical follow-up

## Clinical background of the device

[Device name] was commercialized in Europe for the first time in YYYY. During the last XX years, YY devices were sold in the EU. OR The [Device name] has not yet entered the European market (For new/modified device). The novelty of the device can be described and included along with description of novel design features, if applicable (align the description of the novelty with the CER, if available).

The clinical evidence is based on data from a total of XX clinical investigations conducted for the [Device Name] and YY articles from literature published from DD/MM/YYYY to DD/MM/YYYY. XX post-market clinical trials is/are planned or ongoing.

Overall, the data reports on treatment of YY patients (XX during premarket clinical trials, XX during post-market clinical trials and XX in the literature) who underwent treatment/diagnosis using the [Device Name].

In conclusion, the safety and performance of the devices has been well documented and published.

## The clinical evidence for the CE-marking

### Summary of manufacturer-sponsored clinical studies

The following table includes the premarket and post-market [Manufacturer name]-sponsored clinical trials for [Device Name].

| **Title** | **Status** | **Clinical trial identifiers and link** |
| --- | --- | --- |
| Premarket clinical trial | | |
|  | Complete/ongoing | NCT |
| Post-market clinical trial | | |
|  |  |  |

The following table presents the key safety and performance results for [device Name] from the clinical trials.

| **Key Safety and Performance Endpoint** | **Timepoint** | **Reported Results** |
| --- | --- | --- |
| **Safety** | | |
|  |  |  |
| **Performance** | | |
|  |  |  |

### Summary of clinical data from published clinical literature

The following table presents the key safety and performance results for [device name] from the thorough review of literature. The citations of the articles on [device name] are available in **Section 8**.

| **Key Safety and Performance Endpoint** | **Timepoint** | **Reported Results** |
| --- | --- | --- |
| **Safety** | | |
|  |  |  |
| **Performance** | | |
|  |  |  |

## Safety

[Manufacturer name] assessed all clinical data available on [device name] and concluded that the benefits of treatment/diagnosis using [device name] exceed the possible risks when used as intended.

[Manufacturer name] continuously monitors devices being used by doctors. This helps to confirm whether the devices are safe and perform as expected. This also helps to detect any new or modified risks on the market to define, conduct and verify the necessary actions to control the risks identified. [Manufacturer name] is made aware of safety incidents in a variety of ways, including:

* Concerns or comments from doctors and patients,
* Published literature,
* Clinical trials

# Possible diagnostic or therapeutic alternatives

When considering alternative treatments/diagnosis, it is recommended to contact your healthcare professional who can take into account your individual situation.

## General description of therapeutic alternatives

Alternatives to the use of [device name] are:

* Include a general description of each therapeutic alternative with terms understandable by a layman.

# Suggested training for users

When the device is used by the patient: indicate the required patient training as specified in the IFU in terms understandable by a layman.

When the device is used by the healthcare professional: indicate the required user qualifications or training as specified in the IFU in terms understandable by a layman.

# Glossary of medical and scientific terms

The table below contains a glossary of medical and scientific terms. If applicable The terms also include clinical markers (marked with an asterisk ‘\*’) that are used in the clinical studies/literature included in this SSCP. The clinical markers help to assess whether the device is safe and working properly.

| Term | Definition |
| --- | --- |
| XXX\* |  |
| YYY |  |
| ZZZ\* |  |

\*Clinical markers

# References

1. Include the citations discussed in this SSCP for patients.