Revision History For 100635704

|  |  |
| --- | --- |
| Revision Number | Summary of Change |
| 7 | * Updated template and execution guidelines * Fixed typo to change TDR to CER in blue box guidance and updated canned statement for standards (Section 8) |
| 6 | * Updated instruction/guidance sections for the following sections: template & execution, SSCP finalization, A-1, 2, 3.1, 3.2, 4.1, 4.2, 5, 5.1, 5.2, 5.3, 5.4, 6, 9.2, 10 and all sections in part B * Modified section content/headings for the following sections: A-1.4, 1.5, 4.1, 5.3.1, 5.3.2, 5.5.1, 8 and B-2, 4 |
| 5 | * Updated to align section references and content with CER template (100503977, Rev. 8). * Changed procedural reference to new SSCP Procedure (100887946) and updated content to align with rev. 2 of procedure. * Added instructions about submitting draft SSCP prior to validation and added section reference for revision history. * Clarified instructions for deleting Part B. * Clarified instructions for document title. * Spelled out acronyms (for FSN, FSCA, and CS) and added acronym (IFU). * Updated guidance for Sections 5.2 – 5.4 to align top findings with clinical data used to support the conformity assessment. * Clarified guidance for applied standards * Added section for bibliography for SOA. * Updated part B-2 – B-7 guidance around readability transformation. * Updated “Description of relevant accessories” header in B-3 to “Description of relevant accessories or devices” per MDCG 2019-9 prose. * Updated canned language for B-4. * Updated “Safety” section header for B-5 to “Safety/Performance” per MDCG 2019-9 prose. |
| 4 | * Updated format to all guidance sections and modified content for sections 1, 3.1, and 3.4 relative to Basic UDI-DIs and section B. Canned language in section B was also modified to increase readability. |
| 3 | * Updated guidance sections for template, section 5.5, and SSCP revision history; clarified section 3.2 previous variants; updated formatting styles. |
| 2 | * Overhauled SSCP form to align with MDCG guidance and Shared Clinical Evaluation Report Template (100503977) |
| 1 | * New Summary of Safety and Clinical Performance |

This form supports 100887946, Franchise Procedure for Summary of Safety and Clinical Performance (Shared).

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| --- |
| TEMPLATE AND EXECUTION GUIDELINES |
| This document is to be used in conjunction with SSCP Procedure with the following guidelines. Note: CER Template References are based on Document # 100503977, Rev. 8. If that is not the current revision, utilize section titles for reference.   * Text highlighted between < brackets > should be updated as applicable. * All information should be sourced from the technical documentation. * Dates should be indicated in the format “DD Month YYYY” (e.g., 24 June 2012). * Any acronyms that are used must be defined first in each section. * The scope of the SSCP may not align with the scope of a single CER. Consult the SSCP Procedure (100887946) and MO Evaluator for guidance on determining appropriate scope. * If more than ONE Basic UDI-DI or subject device variant is in-scope of the SSCP, stratify the data with appropriate references to the Basic UDI-DI (signified by Device Model) and/or variant (e.g., Device Model-Variant; X-A, X-B; Y; Z-A, Z-B, Z-C) throughout the document to allow traceability of the information. * Any information that is too voluminous to include in the body of the SSCP can be added as an appendix subsection in Section 9. A cross-reference to the associated Appendix should be referenced in the body. * The content identified in the section guidance boxes details the required content for the SSCP and includes a reference from which section of the CER template the information can typically be extracted. * As a rule, to maintain the proper footer pagination, new document sections should not be added to change the formatting orientation from “portrait” to “landscapes”. If this is vital to the SSCP, footer pagination will have to be done manually. The template pagination is currently linked to the number of pages in each section. * If the SSCP is associated with a device undergoing a Technical Documentation Assessment (e.g., non-WET implant/class III device or initial WET device in scope expression for Quality certificate), the SSCP should be approved by the Evaluators in the Quality System but not released until the SSCP has been validated by the Notified Body. In this case, the revision date marked as “Draft <X>, pending validation”, and the validation status checked “No”. **The revision history description in the released document should reflect the history for the final validated version only and not the draft versions (i.e., “Initial SSCP” or “Routine update to the SSCP” [or similar]).** If interim updates are required to address NB questions, the revision history should not be updated (other than the draft number) but the new draft must be re-approved but not released until after validation. Each “Draft <X>, pending validation” version should be uploaded to the PLM. Upon notification of validation, the “Draft” watermark should be removed, and the revision history updated to reflect the validated status and the SSCP re-approved and released in the Quality System. See Table below for potential versioning. No content changes (other than removing the draft watermark and updating the revision history box) are allowed between the DRAFT SSCP accepted by the NB and the final validated version.  | Step in Process | Approval / Release Status | Date Revision Issued | Change Description | Revision Validated by the Notified Body | | --- | --- | --- | --- | --- | | Initial Submission to NB | Approved by Evaluators  Released | Draft 1, pending validation | Initial SSCP | Yes; Validation Language: English  No | | Resubmitted to address NB Questions | Approved by Evaluators  Released | Draft 2, pending validation | Initial SSCP | Yes; Validation Language: English  No | | After NB has approved SSCP for Validation | Approved by Evaluators  Released | <MMM YYYY> | Initial SSCP | Yes; Validation Language: English  No |  * If the SSCP is NOT associated with a device undergoing a Technical Documentation Assessment (e.g., WET device with existing scope expression), remove the “Draft” watermark before uploading the SSCP for approval/release in the Quality System. * Prior to uploading any SSCP into the document control system, delete the form header, form revision history, template and execution guidelines section, and section guidance boxes. * For SSCPs with a Part B, the SSCP Part B Worksheet must also be uploaded to the PLM as an attachment to the SSCP. Both pdf and Word versions should be uploaded. * For class IIb devices that do not require an implant card and for class III devices that are not intended to be used directly by the patient, Section B is not required and may be deleted. Ensure Section A headers and footers are still correct upon deletion. * Note: Prior to deleting Part B, link Part B header AND footer to previous section by selecting “Link to Previous” once in header AND footer. Otherwise, deletion may change part A header/footer. |

| SSCP FINALIZATION GUIDELINES | |
| --- | --- |
| ü | Action |
|  | **Technical Writer:** Prior to sending document for any Technical Reviews,   * proofread the document with “proofread function in Word”. * check for data and nomenclature continuity from source documents and throughout the document. * check all tables to ensure no blank cells. If cell is not applicable, indicate lack of data as appropriate (e.g., N/A [with explanation], -, 0). If whole row or column is blank, delete it. * ensure hyperlinks to citations are not included in the CER as these may create Good Documentation Practice errors if the hyperlink is changed. (Note: direct citation may be reference but should not include weblink).   hit Control-A to select all, Function F9, and update entire table (if asked) to update all cross references. Then search for key words such as “error!”, “fail”, “attachment”, “section 0” and conduct a spelling review to find inadvertent errors and ensure sequential numbering. Repeat this until no errors are found. |
|  | **MO Evaluator:** Prior to uploading the document for approval, hit Control-A to select all, Function F9, and update entire table (if asked) to update all cross references. Then search for key words such as “error!” and “section 0 and ensure sequential numbering for both the Word and PDF versions. If errors found, send back to Technical Writer of fix (as appropriate). |
|  | **MO Evaluator:** Prior to uploading into document control system, ensure the form header, form revision history, template and execution guidelines, and section guidelines have been deleted. Also check that headers and footers for Section A and B (if appropriate) are correct. |

Part A of 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 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 users/healthcare professionals.

# Device identification and general information

| This section should include the following content (as appropriate): |
| --- |
| Information for this section can typically be extracted from CER Sections identified below.   | SSCP Section | CER Section | | --- | --- | | A-1.1 Trade name(s)  This is the system/device name(s) as identified on the device label(s). | * Section 2 – Administrative Information – Refer to Device Group Name for Tradename and Basic UDI-DI * Section 3.1 – Subject Device Overview | | A-1.2 Manufacturer’s name and address | | A-1.3 Legal Manufacturer’s SRN | | A-1.4 Basic UDI-DI (BUDI-DI)   * The Device Model associated with the BUDI-DI group and the BUDI-DI value should be entered here for all devices in scope of the SSCP. * A BUDI-DI can only be in a single SSCP. | | A-1.5 European Medical Device Nomenclature   * If the scope of the SSCP covers more than one medical device nomenclature, stratify the nomenclature by variant. * The Medical Device Nomenclature numbers and descriptions should reflect the European Medical Device Nomenclature (EMDN). If this is not yet available, indicate this. | | A-1.6 Class of Device | | A-1.7 Year of first certificate (CE)   * This could be MDD or MDR certificate | | A-1.8 Authorized representative / SRN | | A-1.9 Notified Body name and number | |

## Device trade name(s)

<@meta20230117001@>

## Manufacturer; name and address

<@meta20230117002@>

## Manufacturer’s single registration number (SRN)

<@meta20230117003@>

## Basic UDI-DI (BUDI-DI)

Table : BUDI-DI Grouping(s)

|  |  |
| --- | --- |
| Device Model | BUDI-DI Value |
| <@meta20230117004@> | <@meta20230117005@> |

## European Medical Device Nomenclature (EMDN) code – description

<@meta20230117006@>

## Class of device

<@meta20230117007@>

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

<@meta20230117008@>

## Authorised representative if applicable; name and the SRN

<@meta20230117009@>

## Name of Notified body (NB) and the NB’s single identification number

<@meta20230117010@>

# Intended use of the device

| This section should include the following content (as appropriate): |
| --- |
| Information for this section can typically be extracted from CER Sections identified below.   | SSCP Section | CER Section | | --- | --- | | A-2.1 Intended use | * Section 3.1 – Subject Device Overview or Sections 3.1.1 – 3.1.X – Device Description | | A-2.2 Indication(s) | | A-2.2 Target populations | | A-2.3 Contraindications and / or limitations | |

## Intended use

<@meta20230117011@>

## Indication(s) and target population(s)

Indication(s):

<@meta20230117012@>

Target Population:

<@meta20230117013@>

## Contraindications and/or limitations

Contraindication(s)

<@meta20230117014@>

Limitations:

<@meta20230117015@>

# Device description

## Description of the device

| This section should include the following content (as appropriate): |
| --- |
| Information for this section can typically be extracted from CER Sections identified below. Provide a description of the subject device(s), including the elements below. A picture or drawing can be added accompanied by text.   | SSCP Section A-3.1 | CER Section | | --- | --- | | * Design characteristics, for example key functional elements | * Section 3.1 – Subject Device Overview or Sections 3.1.1 – 3.1.X – Device Description | | * Any materials or substances in contact with the patient’s tissues | | * Identify device lifetime. * For absorbable implants, discuss the stability retention profile, including time to loss of stability and the absorption time | | * If the device contains or incorporates: * a medicinal substance, including human blood or plasma derivative * tissue(s) or cells, or their derivatives, of human origin * tissue(s) or cells, or their derivatives, of animal origin (per EU Reg No. 722/2012) * a substance that is absorbed or dispersed in body (for devices intended to be introduced via a body orifice or applied to the skin) * a restricted substance (i.e., CMR [carcinogenic, mutagenic or toxic to reproduction] substances or endocrine-disrupting substances) * materials that could result in sensitization or allergic reaction | | * Whether the device is for single use | | * Method of sterilization | | * Operating principles and mode(s) of action | |

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## A reference to previous generation(s) or variants if such exist, and a description of the differences

| This section should include the following content (as appropriate): |
| --- |
| Information for this section can typically be extracted from CER Sections identified below.   |  |  | | --- | --- | | SSCP Section A-3.2 | CER Section | | * Descriptions of previous generations and the differences from the device(s) in scope | * Section 3.1– Subject Device Overview or Sections 3.1.1 – 3.1.X – Device Description | | * Description of variants within the BUDI-DI group and differences between variants | | * High level reasons for changes/different variants | |

Previous Generation(s):

<@meta20230117017@>

Variants:

<@meta20230117018@>

## Description of any accessories, which are intended to be used in combination with the device

| This section should include the following content (as appropriate): |
| --- |
| Information for this section can typically be extracted from CER Section identified below.   | SSCP Section A-3.3 | CER Section | | --- | --- | | * Description of any accessories that are essential for the safe and correct use of the subject device(s) (if applicable). * Note: Other medical devices used in combination with the subject device(s) should not be included here. These are not “accessories”. | * Section 3.3 – Accessories and Compatible Devices | |

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## Description of other devices and products which are intended to be used in combination with the device

| This section should include the following content (as appropriate): |
| --- |
| Information for this section can typically be extracted from CER Sections identified below.   | SSCP Section A-3.4 | CER Section | | --- | --- | | * Description of any other medical devices (including reference to the Device Model(s) associated with the BUDI-DI group(s) and the BUDI-DI value[s]) intended to be used in combination with the subject device (if applicable). Note: Generic surgical equipment and/or other generic devices do not need to be listed. | * Section 3.3 – Accessories and Compatible Devices | |

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# Risks and warnings

## Potential adverse events, residual risks, and undesirable effects

| This section should include the following content (as appropriate): |
| --- |
| Information for this section can typically be extracted from CER Sections identified below and in [brackets]. Stratify by BUDI-DI group, as appropriate.   | SSCP Section A-4.1 | CER Section | | --- | --- | | * Provide a description of any residual risks and undesirable side effects/adverse event experienced or measured by the patient, as identified in the IFU. | * Section 3.1 – Subject Device Overview or Sections 3.1.1 – 3.1.X – Device Description | | * As the definition of risk includes the probability of occurrence of harm, also include: * Quantification of the identified risks for the subject device(s) from all clinical data sources. * Order the residual risks in the same order that is in the IFU. * If reactive data sources are used, include a comment that there may be significant under-reporting. * When presenting the quantitative data, include a relation to time (e.g., per x years of uses from implantation, per 100 patient-years, reported follow-up time, follow-up period). | * Section 8.1.2 – Clinical Risks / Safety Analysis | |

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## Warnings and precautions

| This section should include the following content (as appropriate): |
| --- |
| Information for this section can typically be extracted from CER Sections identified below. Stratify by BUDI-DI group, as appropriate.   | SSCP Section A-4.2 | CER Section | | --- | --- | | * Identify all warnings and precautions pertaining to the subject device(s) (as documented in the IFU or promotional material). * Warnings and precautions solely related to special procedural steps can be discussed on a general level in the SSCP if a link (URL) to the IFU on the manufacturer’s website is provided | * Section 3.1– Subject Device Overview or Sections 3.1.1 – 3.1.X – Device Description | | * If any particular clinical follow-up is necessary and mentioned in the IFU, that information should also be included in the SSCP | | * Always include any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions. Note: These may be found in other sections (e.g., MRI section) of the IFU. Do not include description of MRI compatibility/testing, only associated warnings/precautions. | |

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## Other relevant aspects of safety, including a summary of any field safety action (Field Safety Notice [FSN] or Field Safety Corrective Action [FSCA]) if applicable

| This section should include the following content (as appropriate): |
| --- |
| Information for this section can typically be extracted from CER Section identified below.   | SSCP Section A-4.3 | CER Section | | --- | --- | | * Identify if the device has been subject to any field safety action (FSCA and FSN), the date of the FSCA and a summary of the associated circumstances and any actions undertaken should also be included. | * Section 6.1.2 – Actions / Alerts | |

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# Summary of clinical evaluation and post-market clinical follow-up (PMCF)

| This section should include the following content (as appropriate): |
| --- |
| Information for this section can typically be extracted from CER Sections identified below. Provide a high-level summary of the overall clinical performance and safety of the subject and / or equivalent device(s), including:   | SSCP Section A-5 | CER Section | | --- | --- | | * Description of the clinical data sources included for confirmation of conformity with relevant GSPRs. | * Section 3.6.1 – Overview of Clinical Data or Summary of Clinical Data Sources and Outcomes Table in Section 8.4 – Conclusion (if available) | | * Description of the key clinical outcome measures. * If other outcomes are widely reported but not considered key outcomes, explanation of why these are not considered key outcomes. * If outcomes are linked to a particular follow-up period associated with the expected lifetime of the device, this should be described. | * Section 3.9.5 – Key Outcome Parameters / Benefit-Risk Acceptability Criteria or Summary of Clinical Data Sources and Outcomes Table in Section 8.4 – Conclusion (if available) | |

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## Summary of clinical data related to equivalent device, if applicable

| This section should include the following content (as appropriate): |
| --- |
| Information for this section can typically be extracted from CER Sections or other references identified below. Stratify by device variant/indication/population/other or aggregate (e.g., for construct), as appropriate. Provide information for the equivalent device(s) (if applicable), including:   | SSCP Section A-5.1 | CER Section or Other Reference | | --- | --- | | * Statement if conformity of the subject device was assessed and endorsed by the NB on the basis of equivalence | * Section 3.8.1 – Demonstration of Equivalence | | * Name of equivalent device(s) with name of manufacturer | | * Device Model(s) associated with the BUDI-DI group(s) and the BUDI-DI value(s) (if available) of the equivalent device(s) | * Appendix 9.2 – Product Codes | | * Statement whether the equivalent device’s SSCP is available in EUDAMED | * Confirm with RA Evaluator | | * Clear reference to type of data sources used | * Section 3.6.1 – Overview of Clinical Data | | * Summary of the clinical data for the equivalent device and how long-term safety and performance of the equivalent device has been confirmed | * Section 8.1 – Data Summary and Benefit-Risk Analysis | |

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## Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable

| This section should include the following content (as appropriate): |
| --- |
| Information for this section can typically be extracted from CER Sections or other references identified below. Provide information for the subject device(s) if premarket clinical investigation(s) were conducted that were used to support the conformity assessment. **Quantitatively summarize the key outcome parameters****. Qualitatively summarize other performance and safety outcomes and identify potentially new/emerging risks.** Subsections should be included for each study. Stratify by device variant/indication/ population/other or aggregate (e.g., for construct), as appropriate. Information to be summarized, include:   | SSCP Section A-5.2 | CER Section or Other Reference | | --- | --- | | * Identification of the investigation. * If performed under the Medical Device Directives or the MDR, identify the CIV ID or single identification number. * Add reference details if the clinical investigation report is available in EUDAMED. * For other studies, the title of the study and a clear reference to a clinical trials database or publication where detailed data on the study can be found should be included. * In the circumstance that the investigation was conducted outside EU, identify the country/-ies where it was performed. | * Section 3.6.1 – Overview of Clinical Data (stratification groups) * Section 5.1 – Clinical Investigations * Section 8.1 – Data Summary and Benefit-Risk Analysis | | * Identity of the device descriptively including any model number/version | | * Intended use of the device in the investigation | | * Objectives of the study | | * Study design: randomized controlled trial, other pivotal trial, short-term feasibility study, other; and the duration of the follow-up | | * Primary and secondary endpoint(s) | | * Inclusion/exclusion criteria for subject selection | | * Number of enrolled subjects for the subject device only, 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 study methods | | * Summary of results: * clinical benefits * undesirable side-effects or adverse events, and their frequency in relation to time * results on long-term benefits or risks, for example implant survival rates at 5 or 10 years and/or cumulative experience in patient-years * a statement of percentage completeness of follow-up * a note if the study is still ongoing for long-term follow up * limitations of the study, such as high loss to follow-up, or potential confounding factors that may question the results. * Any device deficiency and any device replacements related to safety and/or performance during the study. | |

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## Summary of clinical data from other sources, if applicable (Add / delete sub-sections, as appropriate)

| This section should include the following content (as appropriate): |
| --- |
| * Information for this section can typically be extracted from CER Sections identified below. Provide information for the subject device(s) if clinical data were obtained from other sources. Add subsections for each clinical data source type that was used to support the conformity assessment. Stratify by device variant/indication/population/other or aggregate (e.g., for construct), as appropriate. Information to be summarized, include:  | SSCP Section A-5.3 | CER Section | | --- | --- | | * Summary of main findings from systematic literature review with focus on key outcome parameters and potential emerging risks. | * Section 3.6.1 – Overview of Clinical Data (stratification groups) * Section 4 – Device-Specific Systematic Literature Review * Section 8.1 – Data Summary and Benefit-Risk Analysis | | * Cross-reference to a bibliography of included literature (in Appendix 9) from systematic literature review. | * Appendix 9.4.4 – Device-Specific Systematic Literature Appraisal Summary | | * Summary of main clinically relevant findings from the implementation of PMCF plans. **Quantitatively summarize the key outcome parameters. Qualitatively summarize other performance and safety outcomes and identify p**otentially **new/emerging risks.** * Include information on each activity (as applicable) per SSCP section A-5.2 * Identify new or changed likelihood of undesirable side-effect(s), increase in the number or severity of incidents, or any identified trends from PMCF * Identify any known limitations such as incomplete follow-up | * Section 6.2 – Ongoing or Completed PMCF * Section 8.1 – Data Summary and Benefit-Risk Analysis | |

### Systematic Literature Review

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### Post-market Clinical Follow-Up

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## An overall summary of the clinical performance and safety

| This section should include the following content (as appropriate): |
| --- |
| Information for this section can typically be extracted from CER Sections identified below. Provide a high-level summary of the clinical data used to support the conformity assessment, including the overall clinical performance and safety of the subject and / or equivalent device(s). This should include:   | SSCP Section A-5.4 | CER Section | | --- | --- | | * Description of the documented clinical benefits and clinical claims in the IFU and/or promotional material. | * Section 3.6.1 – Overview of Clinical Data (Expected clinical benefits) * Section 3.1– Subject Device Overview or Sections 3.1.1 – 3.1.X – Device Description (Clinical claims) | | * Summary of the overall safety and performance relative to the lifetime of the device as measured by the key outcome parameters. | * SSCP Sections 5.1 – 5.3 | | * Benefit-risk assessment for the various indications including a summary of the evaluation of undesirable side-effects and the acceptability of the benefit-risk ratio | * Section 8.1.5 – Benefit-Risk Profile Acceptability | |

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## Ongoing or planned PMCF

| This section should include the following content (as appropriate): |
| --- |
| Information for this section can typically be extracted from CER Sections or other references identified in brackets below. Add subsections (as warranted) for each PMCF Activity.   | SSCP Section A-5.5 | CER Section | | --- | --- | | * Provide a summary of the latest approved PMCF plan for the subject device(s), including: * a brief description of planned or ongoing activities * if there are any unanswered questions relating to the use of the device and how they will be investigated. | * Section 8.2 – PMCF Assessment | | * Identify if any potential emerging risks, complications or unexpected device failures have been detected, and how these will be followed up. | |

### <Ongoing or Planned PMCF Activity – PMCF Activity Type>

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# Possible diagnostic or therapeutic alternatives

| This section should include the following content (as appropriate): |
| --- |
| Information for this section can typically be extracted from CER Sections identified below.   | SSCP Section A-6 | CER Sections | | --- | --- | | * Identify the relevant diagnostic or therapeutic alternative(s) within the SOA and provide a high-level summary of the overall benefit-risk assessment of these treatment options relative to the subject device(s), including a reference to relevant recognized guidance documents generated by specialty medical societies or educational bodies (if applicable). * Bibliographic references (utilizing Endnote citations) | * Section 3.9.4 – Treatment Options and Interventions * Section 3.9.6 – SOA Conclusions | |

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# Suggested profile and training for users

| This section should include the following content (as appropriate): |
| --- |
| Information for this section can typically be extracted from CER Sections identified below.   | SSCP Section A-7 | CER Section | | --- | --- | | * Identify the suggested profile and training for healthcare professionals and patients (if applicable), including: * any specific mandatory training before using the device, and any update training for continued safe use of the device. | * Section3.1– Subject Device Overview or Sections 3.1.1 – 3.1.X – Device Description | |

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# Reference to any harmonised standards and Common Specifications (CS) applied

| This section should include the following content (as appropriate): |
| --- |
| Information for this section can typically be extracted from the Technical Documentation as identified in the following CER Section.   | SSCP Section A-8 | CER Section | | --- | --- | | * Identify list of applied standards, including (at a minimum): * all applicable applied common specifications (CS) * all applicable international standards harmonized under MDD and/or the MDR * all applicable monographs of the European Pharmacopeia * NOTE: List should NOT include reference to Directives, Regulations, Guidance Documents, or similar. Other pertinent national or international standards may be included. | * Section 2 – Section A Content | | * The year / revision should be documented along with the compliance status (i.e., whether it was applied in full or in part). | |

# Appendi<x/cies>

| This section should include the following content (as appropriate): |
| --- |
| Add subsections in order of reference from body (as warranted).   | SSCP Section A-9 | CER Section | | --- | --- | | * Add other CER bibliographies (or portions thereof), as warranted. | * Appendix 9.4 – Bibliography | |

## Included Literature Bibliography

| This section should include the following content (as appropriate): |
| --- |
| Information for this section can typically be extracted from CER Sections identified below.   | SSCP Section A-9.2 | CER Section | | --- | --- | | * Include bibliography of included literature used for conformity assessment as summarized in SSCP Sections 5.1 – 5.3.X. | * Appendix 9.6.3.1 – References of Sufficient Quality/Relevance to Support Performance / Safety Conformity Assessment | |

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## Included <Diagnostic or Therapeutic> Alternatives Bibliography

| This section should include the following content (as appropriate): |
| --- |
| This section should include the automatically generated endnote citations from the included references.   | SSCP Section A-9.2 | CER Section | | --- | --- | | * Include Endnote bibliography of included literature used for SSCP Section 6. * Note: Ensure only the bibliographies associated with identified references have been included. | * Appendix 9.6.1 – SOA Included Publications & General Publications | |

Carulli, C., Matassi, F., Soderi, S., Sirleo, L., Munz, G., and Innocenti, M. (2017). Resorbable screw and sheath versus resorbable interference screw and staples for ACL reconstruction: a comparison of two tibial fixation methods. Knee Surg Sports Traumatol Arthrosc *25*, 1264-1271.

Debieux, P., Franciozi, C.E.S., Lenza, M., Tamaoki, M.J., Magnussen, R.A., Faloppa, F., and Belloti, J.C. (2016). Bioabsorbable versus metallic interference screws for graft fixation in anterior cruciate ligament reconstruction. Cochrane Database of Systematic Reviews *2016*, no pagination.

Herickhoff, P.K., Safran, M.R., Yung, P., and Chan, K.-M. (2017). Pros and Cons of Different ACL Graft Fixation Devices. In Controversies in the Technical Aspects of ACL Reconstruction: An Evidence-Based Medicine Approach, N. Nakamura, S. Zaffagnini, R.G. Marx, and V. Musahl, eds. (Berlin, Heidelberg: Springer Berlin Heidelberg), pp. 277-288.

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## <New Appendix Title> <add or delete as warranted>

<Insert text or table, as appropriate>

# SSCP Revision History

| **This section should include the following content (as appropriate):** |
| --- |
| Some information for this section can typically be extracted from the references identified below Information required includes:   | SSCP Revision History | Other Reference | | --- | --- | | * SSCP number and revision | * Appendix 9.1.2 – MDR Supporting References for Key Documents | | * Date revision issued * If the SSCP is associated with a device undergoing a Technical Documentation Assessment (e.g., non-WET device or initial WET device in scope expression for Quality certificate), mark the revision date as “Draft <X>, pending validation”, where “X” is 1, 2, n. Identify the draft number in the filename. * Identify month and year (i.e., Mon YYYY) version is expected to be released through Quality System. * Confirm release date of any previously released revisions and put actual date (DD Mon YYYY). | * Document Control System (previous SSCP) | | * Succinct description of the main changes (e.g., Initial SSCP, Routine update to sections 4, 5, and 9). | * N/A | | * Whether the SSCP revision will be validated by the NB * Select “No” if SSCP revision has not yet been validated. * Select “Yes” if SSCP revision has been validated by the NB. * If previous revision(s) had validation marked “Yes” but revision was not validated, correct revision(s) to reflect they were not validated and just note in the change description that it was a “Draft SSCP”. | * N/A | |

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