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Summary of safety and clinical performance

A guide for manufacturers and notified bodies

March 2022

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MDCG 2019-9 Rev.1 changes	
section 3.1	clarification on the association of the SSCP with the Basic UDI-DI in EUDAMED
general requirements and template	addition of a manufacturer reference number

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Introduction

The Regulation (EU) 2017/745 on medical devices (1) requires that the manufacturer shall draw up a summary of safety and clinical performance (SSCP) for implantable devices and for class III devices, other than custom-made or investigational devices. The SSCP shall be validated by a notified body (NB) and made available to the public via the European database on medical devices (Eudamed)[1].

The SSCP is intended to provide public access to an updated summary of clinical data[2] and other information about the safety and clinical performance of the medical device. The SSCP will be an important source of information for intended users – both healthcare professionals and if relevant for patients. It is one of several means intended to fulfil the objectives of the Medical Device Regulation (MDR) to enhance transparency and provide adequate access to information[3].

The SSCP is not intended to:

- give general advice on the diagnosis or treatment of particular medical conditions, nor
- replace the instructions for use (IFU) as the main document that will be provided to ensure the safe use of a particular device, nor
- replace the mandatory information on implant cards[4] or in any other mandatory documents.

The main purpose of this document is to provide guidance on the presentation, content and validation of the SSCP. The word “shall” is used when there is a corresponding “shall” in the MDR, otherwise “should” or “recommended” etc. is used indicating the interpretation of the MDR.

Abbreviations

CIV ID	clinical investigation identification number, generated by Eudamed for clinical investigations under the Medical Device Directives (2) (3)
CMR	carcinogenic, mutagenic or toxic to reproduction
CS	‘common specifications’ as defined in the MDR[5]
EU	European Union
Eudamed	European database on medical devices
FSCA	field safety corrective action[6]
FSN	field safety notice[7]
IFU	instructions for use
MDR	Medical Device Regulation (1)

[1] MDR, Article 32 (1)
[2] MDR, Article 32 (2)(f) , Article 61 (11) and Article 83 (3)(d)
[3] MDR, Recital (43)
[4] MDR, Article 18
[5] MDR, Article 2 (71)
[6] MDR, Article 2 (68)
[7] MDR, Article 2(69)

NB	notified body[8]
PMCF	post-market clinical follow-up[9]
PMS	post-market surveillance[10]
PSUR	periodic safety update report[11]
SRN	single registration number for an economic operator[12]
SSCP	summary of safety and clinical performance
TD	technical documentation[13]
UDI-DI	Unique Device Identification - device identifier[14]
URL	Uniform Resource Locator (internet address)

General requirements and recommendations for the SSCP

The information in the SSCP should be sourced entirely from the technical documentation (TD) of the device[15]. Examples of such documents are design verification/validation reports, the risk management report/file, the clinical evaluation report, and post-market surveillance (PMS) and post-market clinical follow-up (PMCF) plans and reports. The IFU includes information extracted from the same sources as the SSCP, but may itself be used as a source for the SSCP if appropriate.

The manufacturer will assign to the SSCP an identifier (reference number) that within the manufacturer's management system is unique to that SSCP and will remain the same for the entire lifetime of the SSCP. In combination with the manufacturer's SRN this will allow for the unique identification of the SSCP in EUDAMED and in EU.

The SSCP shall be kept updated in Eudamed[16]. When the PMCF evaluation report[17] and the periodic safety update report (PSUR)[18] are updated at least annually[19], the SSCP shall be reviewed and updated[20] if needed to ensure that any clinical and/or safety information in the SSCP remains correct and complete. When updating the SSCP, all sections of the document shall be updated if needed so that they are in alignment with the most current version of the relevant parts of the TD of the device.

This guide outlines the minimum content of the SSCP. The manufacturer may add further information from the TD of the device to enhance the comprehension of the mandatory information providing:

[8] MDR, Article 2 (42)
[9] MDR, Annex XIV Part B
[10] MDR, Article 2 (60)
[11] MDR, Article 86 Periodic safety update report
[12] MDR, Article 31(2)
[13] MDR, as specified in Annexes II and III.
[14] MDR, Article 2 (15) and Article 27
[15] MDR, Annex II and III
[16] MDR, Article 29 (4) and Annex VI Part A 2.14
[17] MDR, Article 61 (11)
[18] MDR, Article 86 (1)
[19] MDR Article 86 (1); PSUR for class IIa devices shall be updated when necessary and at least every two years
[20] MDR, Article 61 (11) and Article 83 (3)(d)

- it does not affect the readability of the SSCP and
- it excludes any element of a promotional nature.

The SSCP shall be objective and adequately summarise both favourable and unfavourable data[21].

For further guidance on the contents of the SSCP, please refer to sections 1-8 of this document and to the template in the Appendix. The format and structure of this template is recommended. It addresses all of the SSCP content requirements of the MDR[22], but the order has been revised to enhance its presentation.

The IFU shall contain all that is needed to directly find the SSCP in Eudamed. The following applies to the IFU[23].

- It shall state that the SSCP is available in the European database on medical devices (Eudamed), where it is linked to the Basic UDI-DI.
- It should provide the URL to the Eudamed public website: https://ec.europa.eu/tools/eudamed
- It should state the value of the Basic UDI-DI. Alternatively, another metadata can be stated provided it can be used to unambiguously search and find the intended SSCP in Eudamed.

Translations to other EU languages

No single language will be understood by all intended users and patients in the EU – see the European Survey on Language Competences initiated by the European Commission (4). In order to meet the requirement in the MDR that the SSCP shall be written in a way that is clear to the intended user and, if relevant, to the patient[24], the SSCP should be translated into the languages accepted in the Member States where the device is envisaged to be sold. This is by analogy with the requirement for an IFU[25]. Note that Member States may have different language requirements for an IFU depending on whether the information is intended for health care professionals or for patients. The SSCP part intended for patients should be provided in all the languages required for IFUs intended for patients in the Member States concerned.

If the selection of European languages for the SSCP does not include English, then an English translation of the document should also be provided. English is the most common language used in medical scientific publications and is understood by many healthcare professionals in the EU. Always providing an English-language version of the SSCP further enhances access to information[26] about devices available on the EU market.

There should be one SSCP document for each language. Each SSCP document should state in which language the SSCP was validated by the NB. The manufacturer should ensure, through their quality management system, that the

[21] MDR, Annex XIV, Part A Clinical evaluation, (2)
[22] MDR, Article 32 (2)
[23] MDR, Article 32 (1) and Annex I, 23.4 (d)
[24] MDR, Article 32 (1) and Recital (43)
[25] MDR, Annex II (2), Article 10 (11)
[26] MDR, Recital (43)

translations are correct.

Relevant SSCP information for patients

The MDR indicates that patients are also intended recipients of the information in the SSCP, "if relevant"[27]. Devices for which information will be especially relevant for patients include:

- implantable devices for which patients will be given implant cards[28], and
- class III devices that are intended to be used directly by patients.

For these devices, a part of the SSCP specifically intended for patients should be provided.

Note: Devices listed in MDR Annex XVI, and eligible for a SSCP, should always be considered as relevant for patient information.

For devices other than the two groups listed above, including any devices listed in Annex XVI and eligible for a SSCP, the manufacturer may consider whether it is relevant to provide specific information intended for patients. This can be based on the manufacturer's analysis of the device in question.

Readability

The SSCP should always have one part for intended users/healthcare professionals, and when it is relevant (see above) a second part for patients. Both should be clear and provide information at an appropriate depth to reflect the healthcare professionals' and the patients' different levels of knowledge[29].

For further guidance, see references (5) and (6) in this guide. It should not be assumed that the patient has any formal education in a medical discipline or any prior knowledge of medical terminology or clinical research. It is recommended that the readability of the part of the SSCP intended for patients is assessed for example by a test given to lay persons. The manufacturer may use a method it finds adequate for the readability test to confirm that the SSCP is written in a way that is clear to the patient[30].

Medical terminology, relevant for the medical device and the clinical context, should be used consistently throughout the part of the SSCP that is intended for healthcare professionals.

Stylistic recommendations

The SSCP should be presented in an organised and unambiguous manner.

Usually, abbreviations and acronyms should not be used; if they are, then in the text, the abbreviation or acronym should follow the full phrase it is intended to replace. It may then be used thereafter throughout the document.

[27] MDR, Article 32 (1)
[28] MDR, Article 18
[29] MDR, Article 32 (1) and Recital (43)
[30] MDR, Article 32(1), Article 2 (38)

Medical terms should be explained in simple language in the parts intended for patients. Consistency should be assured by giving the lay term with a description first, and then the medical term immediately afterwards (in brackets). On a case-by-case basis the lay or medical term (but preferably the lay term) may then be used throughout the part intended for patients.

It is recommended to keep the information for patients/lay persons and for intended users/healthcare professionals in two separate parts of the SSCP, separated by a "page break". This enhances their readability and facilitates printing of each part separately. See the template in the Appendix of this document.

The SSCP should be written in a font type and size which allow easy reading. Since the SSCP is intended for the public, it needs to be in a format that everyone can read (and that is not editable) without the need for a license. Therefore the SSCP file uploaded in Eudamed should be in PDF format. When downloaded, the PDF file should be printable and searchable with the search function in the program used to view the file, for example the Adobe Reader.

Validation and uploading of the SSCP

Validation of the initial SSCP by the NB

When the NB has assessed that all the required elements[31] are included in the draft SSCP, accurately presented and in alignment with the most current version of relevant documents in the TD, the SSCP has been *validated* by the NB.

In the circumstance that the conformity assessment is performed according to Annex X and XI in the MDR and there are two NBs involved, it is the NB which assesses the TD according to Annex X that shall validate the SSCP.

The validation of the SSCP by the NB covers only one of the language(s) accepted by the NB and agreed with the manufacturer. The manufacturer should state in the revision history in each SSCP document in which language the SSCP was validated by the NB.

The timing of the SSCP validation may depend on the class of device and the conformity assessment routes:

- For class III devices and class IIb implantable devices, except sutures and staples etc.[32], the validation is performed when a draft SSCP as a part of the application documents is submitted to the NB involved in the conformity assessment[33], prior to issuing the certificate.
- For class IIa implantable and some IIb implantable devices such as sutures and staples etc[34], a draft SSCP as a part of the application documents shall be submitted to the NB involved in the conformity assessment. The draft SSCP shall be validated by the NB[35].

[31] MDR, Article 32 (2), Article 61 (11), and Article 83 (3) (d)
[32] MDR, Article 52 (4) 2nd paragraph
[33] MDR, Article 32 (1)
[34] MDR, Article 52 (4) 2nd paragraph
[35] MDR, Article 32 (1)

In the circumstance if more than one device is covered by the relevant certificate, at least one draft SSCP shall be validated against relevant documents in the TD during the initial conformity assessment, prior to issuing the certificate.

Draft SSCPs that are not validated at the initial conformity assessment, shall be validated against relevant documents in the TD at least once during the period of validity of the certificate.

Validation of updates of the SSCP between certification activities

The manufacturer has an obligation to keep the SSCP updated; for further details see the section "General requirements and recommendations for the SSCP" in this guide. Furthermore the manufacturer shall prepare a periodic safety update report (PSUR) that includes data gathered as a result of the post-market surveillance plan, description of any preventive and corrective actions taken, conclusions of the benefit-risk determination, and the main findings of the PMCF[36].
If the PSUR contains information rendering any information in the SSCP incorrect or incomplete, the SSCP shall be updated[37] to be in line with the information in the most recent PSUR.

The manufacturer shall submit a PSUR to the NB at least annually, or for class IIa implantable devices[38] at least every two years[39].
If the SSCP has been updated with new/changed information, except for strictly editorial modifications, the manufacturer should submit the updated SSCP to the NB when submitting the required PSUR.

- If the SSCP has been previously validated, the NB should validate the updated SSCP against the submitted and evaluated PSUR. Both the NB and the manufacturer should make an effort to keep the validation time short in order to meet the MDR requirement of an update of the SSCP at least annually if indicated[40].
- If the SSCP has not previously been validated[41], the NB may defer the validation until a validation against the relevant documents in the TD is planned during the period of validity of the certificate.

In addition, as part of its surveillance activities, the NB shall verify that the manufacturer has appropriately updated the SSCP. The NB should take into consideration its assessment of the PMS plan and PSUR, the PMCF plan and its evaluation report, and/or other relevant information.

[36] MDR, Article 86 (1)
[37] MDR, Article 29 (4) and Annex VI Part A 2.14, and Article 61 (11) and Article 83 (3)(d)
[38] In this context applicable for implantable devices intended to be placed in the teeth, MDR Annex VIII, 5.4. Rule 8)
[39] MDR, Article 86 (1)
[40] MDR, Article 61 (11)
[41] May only be applicable for class IIa implantable devices and some IIb implantable devices such as sutures, staples etc. as listed in MDR, Article 52 (4) 2nd paragraph

Validation of SSCP at certificate renewal

With each certificate renewal application, the manufacturer should:

- For class III devices and class IIb implantable devices, other than sutures and staples etc.[42], submit a draft SSCP which has been updated within the previous 12 months, regardless of whether there are new data or conclusions.
- For class IIa implantable and IIb implantable devices, such as sutures and staples etc.[43], confirm that the SSCP in Eudamed is in alignment with the current version of the TD, or provide an updated SSCP where required.

At certificate renewal, the same principles should apply for the validation of the SSCP documents as at the initial certification.

Uploading of the SSCP in Eudamed

The SSCP shall be uploaded in Eudamed by the NB[44], which is the only actor that can manage the SSCPs in Eudamed. Timelines for uploading of the SSCP documents in Eudamed:

- The NB shall upload the SSCP validated in conjunction with an initial conformity assessment at the same time that it uploads the issued certificate.
- For class IIa implantable and IIb implantable devices, such as sutures and staples etc.[45], the NB shall upload the SSCPs of all the devices covered by the issued certificate at the same time that it uploads the issued certificate, even if some of the SSCPs have not been validated yet, and are to be validated during the period of validity of the certificate.
  The manufacturer should state in a revision history in the SSCP document whether that revision was validated by the NB. It is important and should be transparent to the public[46] whether the SSCP document has been validated yet by the NB. See the example of a revision history in section 9 and in the template in the Appendix of this guide.
- The NB shall upload a SSCP whenever it has been validated against relevant documents in the TD, and thus replacing the SSCP uploaded at the initial certification with the currently validated revision.
- The manufacturer is responsible for the translations of the SSCP into other languages[47], once the “master” SSCP has been uploaded by the NB.
  If the “master” SSCP is in a language other than English, then an English translation should be provided by the manufacturer within 90 days of the upload of the “master” SSCP. The NB should upload the English translation within 15 days of receiving this from the manufacturer.
- The manufacturer decides when it translates the initial “master” SSCP into other languages in the Member States depending on when/if they plan to place the product on that market.
  The NB does not validate the translated SSCP documents. It should upload them in Eudamed within 15 days of receiving them.

[42] MDR, Article 52 (4) 2nd paragraph
[43] MDR, Article 52 (4) 2nd paragraph
[44] MDR, Article 32 (1)
[45] MDR, Article 52 (4) 2nd paragraph
[46] MDR, Recital (43)
[47] See page 4 in this guide, Translations to other EU languages; The manufacturer should ensure, through their quality management system, that the translations are correct.

The manufacturer shall verify that the SSCP, and any translations needed for any single Member State, have been uploaded in Eudamed before placing a device on that market[48].

- When receiving an updated SSCP document in conjunction with the PSUR, the NB should upload the updated SSCP document within 15 days after it is validated, or within 15 days after deeming the validation to be deferred[49] until a validation against the relevant documents in the TD is planned during the period of validity of the certificate.
- At certificate renewal, the NB shall upload any updated SSCPs of all the devices covered by the reissued certificate at the same time that it uploads the reissued certificate. The NB should ensure the revision history indicates whether or not these have been validated by the NB.
- The manufacturer should provide updated translations to the NB within 90 days of the upload of the updated "master" SSCP. The NB should upload these translations within 15 days of receiving them from the manufacturer.

Guidance for each of the required sections of the SSCP document

1. The identification of the device and the manufacturer, including the Basic UDI-DI and, if already issued, the SRN

The first section of the SSCP shall identify the device and the manufacturer, and should also contain some general information related to the device:

1.1. Device trade name(s) (this include all trade names the device may have on the market in different Member States)
1.2. Manufacturer's name and address
1.3. Manufacturer's SRN (single registration number)
1.4. Basic UDI-DI
1.5. Medical device nomenclature[50] description / text
1.6. Class of device[51]
1.7. Year when the first certificate (CE) was issued covering the device
1.8. Authorised representative if applicable; name and the SRN
1.9. NB's name (the NB that will validate the SSCP) and the NB's single identification number[52]

[48] MDR, Article 29 (4) and Section 2 of Part A of Annex VI (2.14)
[49] May only be applicable for class IIa implantable devices and some IIb implantable devices as listed in MDR, Article 52 (4) 2nd paragraph
[50] MDR, Article 26
[51] MDR, Annex VIII
[52] MDR, Article 43 (1)

2. The intended purpose of the device and any indications, contraindications and target populations

2.1. The device's intended purpose(s) shall be described.

2.2. The indications shall be described. This includes the stages and/or severities of the pathologies, the specific medical conditions, and the specific anatomical locations or confirmation that no anatomical locations are contraindicated, as applicable. The target population(s) shall be specified, for example if the device is intended for adults and/or children and/or infants/neonates.

2.3. Any contraindications or restrictions for use or limitations of the device shall be included.

The information can be sourced from the IFU, or from the clinical evaluation report.

3. A description of the device, including a reference to previous generation(s) or variants if such exist, and a description of the differences, as well as, where relevant, a description of any accessories, other devices and products, which are intended to be used in combination with the device

3.1. A description of the device shall be presented, including its operating principles and mode(s) of action. Design characteristics should be included, for example key functional elements and any materials or substances in contact with the patient's tissues. Include information on whether the device is for single use, and its method of sterilisation. For absorbable implants the stability retention profile, including time to loss of stability and the absorption time, should be provided.
A picture or drawing can be added accompanied by text.

Information about the constituents should be provided, as required for the IFU[53], if the device incorporates

- a medicinal substance (including a human blood or plasma derivative), or
- tissue(s) or cells of human or animal origin, or their derivatives, or
- substances or combinations of substances that are absorbed by or locally dispersed in the human body, or
- materials incorporated into the device that contain or consist of CMR (carcinogenic, mutagenic or toxic to reproduction) substances or endocrine-disrupting substances, or
- materials that could result in sensitisation or an allergic reaction by the patient or user.

In Eudamed, the SSCP is associated to one or multiple Basic UDI-DI(s). All UDI-DIs/devices associated to this Basic UDI-DI will be seen as having the

[53] MDR, Annex I (23.2) (e) and (r), and (23.4) (s)

same SSCP (a UDI-DI/device must always be associated with one and only one Basic UDI-DI).

If the device is a system of several components/devices, each device in the system should have a Basic UDI-DI but also one Basic UDI-DI for the system. It is the Basic UDI-DI for the system that is intended to be provided in section 1.4 in the template, and that will be associated with the SSCP in Eudamed. The device system, and any Basic UDI-DIs of included devices, should be described in section 3.1.

The device description in the SSCP shall therefore 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 / specification of any soft-ware 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.

3.2. A reference to previous generation(s) or variants shall be provided, if such exist. This applies both to changes/variants of the device itself (same Basic UDI-DI) and to previous generation(s) or variants associated with other Basic UDI-DIs, if available. A description of the differences shall be provided, highlighting the reasons for the change; for example changes to the intended clinical benefits, changes to reduce identified clinical risks, or changes for manufacturing reasons etc.

3.3. If there are any accessories[54] that are not themselves devices, but are intended by the manufacturer to be used in combination with the device, they shall be described or listed. The list of accessories should include all those that are essential for the safe and correct use of the device.

3.4. If there are any other devices and products intended to be used in combination with the device, they shall be described or listed. However, generic surgical equipment and/or other generic devices do not need to be listed.

In the part of the SSCP that is intended for patients, section 3 may be limited to the device(s) in question (Basic UDI-DI) including relevant and necessary accessories from a patient's perspective; see suggested headings for section 3 in the template in the Appendix.

4. Information on any residual risks and any undesirable effects, warnings and precautions

4.1. Residual risks and undesirable effects

[54] MDR, Article 2 (2)

This section of the SSCP guide and template includes residual risks[55], other than those contraindications, limitations, warnings and precautions that are included in sections 2.3 and 4.2.

Description of residual risks and undesirable effects

Risk is defined in the MDR[56] as the combination of the probability of occurrence of harm and the severity of that harm. Harm is defined in the standard ISO 14971:2012[57] as physical injury or damage to the health of people, or damage to property or the environment. Thus the term 'risk' includes both clinical and non-clinical harms.

The term 'residual risk' is defined in the standard ISO 14971:2012[58] as "risk remaining after risk control measures have been taken".

There is a requirement in the MDR that the IFU shall contain information on any residual risks and any undesirable side-effects[59], *i.e.* no sort of residual risk or undesirable side-effect related to the device is excluded from disclosure. The SSCP should contain information on at least the same residual risks and undesirable side-effects as included in the IFU.

For the purpose of the SSCP, an undesirable effect[60] can be understood as any undesirable side-effect related to the device and that is experienced by the patient and/or can be diagnosed and/or measured in the patient.

For the clarity of the SSCP, undesirable side-effects can be annotated also in other terms as appropriate, to present any undesirable side-effects related to the device in question. There may be device-specific terminology for describing side-effects and risks in device-specific ISO standards or scientific literature that is important to use to allow comparison of clinical data.

For example, some events indicated in the MDR by the terms 'adverse events'[61], 'undesirable side-effects' or 'incidents'[62], may all be annotated as 'adverse events' in the scientific literature.
Any further discussion on risks can be included in the SSCP if needed for clarity or comprehension.

Quantitative data

The definition of risk[63] includes the probability of occurrence of harm. Therefore the information in the SSCP on risks shall also include quantifications. This information can be sourced from the clinical evaluation

[55] MDR, Annex I, (23.1) (g)
[56] MDR, Article 2 (23)
[57] EN ISO 14971:2012 Medical devices – Application of risk management to medical devices, section 2.2
[58] EN ISO 14971:2012 Medical devices – Application of risk management to medical devices, section 2.15
[59] MDR, Annex I , 23.4 (g)
[60] MDR, Article 32 (2) (h)
[61] MDR, Article 2 (57)
[62] MDR, Article 2 (64)
[63] MDR, Article 2 (23)

report where an updated examination of qualitative and quantitative aspects of clinical safety is available, with clear reference to the determination of residual risks and side-effects[64].

It should also be clarified in the SSCP whether quantitative data on side-effects or residual risks relate to clinical data that were obtained proactively, for example from a structured prospective follow-up study of the device itself, or if the expected frequencies[65] come from a systematic review of the scientific literature. It should be disclosed in the SSCP if data from spontaneously reported incidents or serious incidents[66] are used as one of the sources for estimating quantitative data on side-effects or residual risks, in which case significant under-reporting needs to be considered.

A relation to time should also be included when presenting the quantitative data, for example during five or ten years of use from implantation, or adverse events per 100 patient-years for implantable devices with constant hazards, etc. The quantitative data and the relation to time should always be presented together.

To use tabulated lists for the presentation of side-effects and residual risks with quantitative data and a relation to time, may enhance the readability.

In the part of the SSCP that is intended for patients, residual risks and side-effects should be explained and quantified in a way that patients and lay persons can understand. A statement should be included about how potential risks have been controlled or managed, and also a statement on what to do if the patient believes that he/she is experiencing side-effects related to the device or its use. See the example in the template in the Appendix.

4.2. All warnings and precautions pertaining to the device should be presented. However warnings and precautions solely related to for example installation/preparation of a device or relating 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.

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.

If any particular clinical follow-up is necessary and mentioned in the IFU, that information should also be included in the SSCP.

4.3. Other relevant aspects of safety should be described. If the device has been subject to any field safety corrective action (FSCA including FSN), the date of

[64] MDR, Annex XIV, Part A Clinical evaluation, (1)
[65] MDR, Article 88 (1)
[66] MDR, Article 2 (64) and (65)

the FSCA and a summary of the associated circumstances and any actions undertaken should also be included.

5. The summary of clinical evaluation as referred to in Annex XIV, and relevant information on post-market clinical follow-up

This part of section 5 relates to content intended for the user/healthcare professional.

This section is intended to summarise, in a comprehensive manner, the clinical evaluation results and the clinical data[67] forming the clinical evidence[68] for the confirmation of conformity with relevant general safety and performance requirements[69], the evaluation of undesirable side-effects and the acceptability of the benefit-risk ratio[70].

It shall be an objective and balanced summary of the clinical evaluation[71] results of all the available clinical data related to the device in question, whether favourable, unfavourable, and/or inconclusive.

See suggested headings for this section in the Appendix of this document.

5.1. The SSCP should include a statement if conformity of the device was assessed and endorsed by the NB on the basis of equivalence. If equivalence was used, then the device(s) for which equivalence has been demonstrated should be identified by name and Basic UDI-DI if available, together with the name(s) of its/their manufacturer(s).

The SSCP should also include a statement whether the equivalent device's SSCP is available in Eudamed. If not available in Eudamed, the SSCP should include a summary of the clinical data pertaining to the equivalent device, written in accordance with the recommendations of this section 5, with a clear note that it relates to the equivalent device. It should be evident from the summary what the clinical evidence for the equivalent device was based on: whether it was clinical investigations of that device itself, or if any other data were used and then the sources of that data. Also include a summary of how long-term safety and performance of the equivalent device has been confirmed.

5.2. All clinical investigations of the device in question, conducted before the CE-marking, should be summarised. It is recommended to keep the format clear by grouping the information for each study. The summary of each investigation should include the following non-exclusive list:

[67] MDR, Article 61 (11) and Article 2 (48)
[68] MDR, Article 2 (51)
[69] MDR, Annex I
[70] MDR, Article 61 (1) and Annex XIV, Part A (1)
[71] MDR, Annex XIV, Part A (2)

- Identity of the investigation/study: If performed under the Medical Device Directives or the MDR, then give the CIV ID or single identification number. Add reference details if the clinical investigation report is available in Eudamed[72]. 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 (7)[73] should be included. In the circumstance that the investigation/study was conducted outside EU, identify the country/-ies where it was performed.
- Identity of the device including any model number/version
- Intended use of the device in the investigation
- Objectives of the study
- Study design: randomised 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, 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: any clinical benefits[74]; any undesirable side-effects or adverse events, and their frequency in relation to time; any 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 should be provided. Add a note if the study is still ongoing for long-term follow up.
- Any 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.

5.3. Summary of other clinical data and the main findings pertaining to the device itself should be included if available.
This can be sourced[75] for example from:

- A systematic literature review yielding articles in which the device in question was used. References to these articles should be provided. A bibliography can be added at the end of the SSCP document if there are many references.
- Clinically relevant information based on clinical data obtained from the implementation of the manufacturer's PMCF and PMS plans, such as:
  - Conducted PMCF investigation(s)[76]; include information on each study as outlined in section 5.2 in this guide.

[72] MDR, Article 77 (7)
[73] WMA Declaration of Helsinki, sections 35, 36, MDR Recital (64)
[74] MDR, Article 2 (53)
[75] MDR, Article 2 (48)
[76] MDR, Article 74 (1)

  - New or changed likelihood of an undesirable side-effect(s), or significant increase in the frequency or severity of incidents, or any identified trends[77], or any other main findings from the PMCF evaluation report or PSUR[78].
- Analysis of clinical data from medical device registries. Any known limitations such as incomplete follow-up should be disclosed.

5.4. An overall summary of the clinical performance[79] and safety should be provided, and that is supported by clinical evidence[80], based on clinical data and the clinical evaluation results pertaining to the device in question. It is recommended that the overall summary should include the following:

- The clinical performance normally leads to clinical benefits for the patient. Give a description of the documented clinical benefits[81] for patients with relevant and specified clinical outcome measures, and the success rate for achieving the outcome measures. This should be described for all clinical claims the manufacturer presents in the IFU, and in any information, marketing, or promotional material that it distributes. For a non-absorbable implant, there should also be information about the expected lifetime of the device including data on implant survival rates.
- Benefit-risk assessment for the various indications including the acceptability of the benefit-risk ratio[82]. This includes a summary of the evaluation of undesirable side-effects.

In the case of a device without an intended medical purpose[83], the requirement to demonstrate clinical benefit shall be understood as a requirement to demonstrate the performance of the device. The summary of the clinical evaluation shall be based on relevant data concerning safety and performance[84].

5.5. The SSCP shall have a section on planned or ongoing PMCF[85] that should include the following (non-exclusive list):

- Summary of the latest approved PMCF plan for the device. Include any planned or ongoing studies (brief description), and if there are any unanswered questions relating to the use of the device and how they will be investigated.
- If any emerging risks, complications or unexpected device failures have been detected, and how these will be followed up.

[77] MDR, Article 88 (1) and Annex XIV Part B (6.1) (b)
[78] MDR, Article 61 (11), Article 83 (3) (d)
[79] MDR, Article 2 (52)
[80] MDR, Article 61 (1) and Article 2 (51)
[81] MDR, Article 2 (53)
[82] MDR, Article 61 (1) and Annex I Sections 1 and 8
[83] MDR, Annex XVI
[84] MDR, Article 61 (9)
[85] MDR, Annex XIV Part B

The information on clinical evaluation and PMCF intended for patients, in section 5

The part of the SSCP intended for patients should be provided with a brief summary which enables the patient to understand the basis upon which clinical safety and performance has been demonstrated. The summary should include the following (non-exclusive list):

- Clinical background of the device
  A description of the relative novelty of the device: if the product has a proven clinical track record of safety and performance, or if there are one or more novel design features.
- The clinical evidence for the CE marking
  A description whether clinical evidence is based on data concerning an equivalent device, on data collected during a clinical investigation of the device itself, or on a combination of the two. A short lay-summary of the clinical investigations performed on the device itself should be given, if such exist. If there are clinical investigation reports on the device itself available in Eudamed, this should be stated and identification numbers should be given[86] (CIV ID or single identification number). The summary should not make misleading claims regarding the strength of clinical evidence, either by direct reporting or omission.
- Safety
  - A description of the benefit-risk assessments related to safety and performance for each indication claimed by the manufacturer, including information to address benefit-risk issues of interest to specific patient populations, if applicable.
  - A description of *how* the manufacturer continuously collects information on safety and performance and in particular if any clinical studies (PMCF) are ongoing or planned. A description of the purpose of any such studies, for example to corroborate safety and performance claims based on equivalence data, or to demonstrate long-term safety.

6. Possible diagnostic or therapeutic alternatives

This part of the SSCP document should contain a review of how the device relates, in terms of benefit-risk, to diagnostic or therapeutic alternatives and the specific conditions under which the device and its alternatives can be considered[87].

If reference is made to the “state of the art”, that statement should be supported for example by referring to relevant recognised guidance documents generated by specialty medical societies or educational bodies.

In the part of the SSCP intended for patients the text should include a recommendation to discuss any possible diagnostic or therapeutic alternatives

[86] MDR, Article 77 (7)
[87] MDR, Recital 49

with a healthcare professional who can take into consideration the individual patient's situation. See the proposed text in the template in the Appendix.

7. Suggested profile and training for users

The experience, education and/or training of the intended user(s) shall be described[88]. This includes any specific mandatory training before using the device, and any update training for continued safe use of the device.

If the device is intended to be handled directly by the patient, section 7 should be included in the SSCP part intended for patients and any required training should be described.

8. Reference to any harmonised standards and CS applied

A list with all applied common specifications (CS), international standards harmonised under the Medical Device Directives (2)(3) and/or the MDR, and relevant adopted monographs of the European Pharmacopoeia[89] shall be provided.

The year/revision of the applied CS, standard or monograph, should be listed together with information whether it was applied in full or in part.

The year/revision of an applied harmonised standard or CS may change in the technical documentation for the device. However, an update of the SSCP concerning this change can wait until the next revision of the SSCP is issued.

This list in section 8 does not need to be included in the part of the SSCP that is intended for patients.

9. Revision history

The SSCP document should include a revision history. The purpose is to include the following information:

- The SSCP revision number
- Date when the revision was issued
- Description of the main changes
- In which language the SSCP was validated by the NB
- In case of a SSCP on class IIa implantable or some[90] IIb implantable devices; whether the SSCP revision has been validated yet or not by the NB

[88] By analogy with the IFU, see MDR, Annex I, 23.1 (a)
[89] MDR, Article 8 (2)
[90] MDR, Article 52 (4) 2nd paragraph

See an example of a table for a Revision history in the Appendix of this guide.

References

1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2017:117:TOC

2. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01993L0042-20071011

3. Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01990L0385-20071011

4. The European Survey on Language Competences: measuring foreign language student proficiency. Patrícia Costa and Patrícia Albergaria-Almeida / Procedia - Social and Behavioral Sciences 191 (2015) 2369 – 2373
https://www.sciencedirect.com/science/article/pii/S187704281502515X

5. Summaries of Clinical Trials Results for Laypersons
https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2017_01_26_summaries_of_ct_results_for_laypersons.pdf

6. Common European Framework of Reference for Languages: Learning, teaching, assessment (CEFR)
https://www.coe.int/en/web/common-european-framework-reference-languages/home

7. WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects
https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

Appendix: Template for the SSCP

Texts in *italic* in the template are general information texts proposed to be included in the SSCP document.

Note that there shall always be SSCP information dedicated to users/healthcare professionals for all implantable devices and for all class III devices, other than custom-made or investigational devices. When relevant, a second part dedicated to patients/lay persons should be added. See further recommendations on relevant SSCP information for patients in this guide.

Summary of safety and clinical performance

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 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.

If the SSCP includes a part intended for patients, the following can be added:
Following this information there is a summary intended for patients.

Manufacturer's reference number for the SSCP

1. Device identification and general information
   - 1.1. Device trade name(s)
   - 1.2. Manufacturer's name and address
   - 1.3. Manufacturer's single registration number (SRN)
   - 1.4. Basic UDI-DI
   - 1.5. Medical device nomenclature description / text
   - 1.6. Class of device
   - 1.7. Year when the first certificate (CE) was issued covering the device
   - 1.8. Authorised representative if applicable; name and the SRN
   - 1.9. NB's name (the NB that will validate the SSCP) and the NB's single identification number

2. Intended use of the device
   - 2.1. Intended purpose
   - 2.2. Indication(s) and target population(s)
   - 2.3. Contraindications and/or limitations

3. Device description
   - 3.1. Description of the device
   - 3.2. A reference to previous generation(s) or variants if such exist, and a description of the differences
   - 3.3. Description of any accessories which are intended to be used in combination with the device
   - 3.4. Description of any other devices and products which are intended to be used in combination with the device

4. Risks and warnings
   - 4.1. Residual risks and undesirable effects
   - 4.2. Warnings and precautions
   - 4.3. Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)
   - 5.1. Summary of clinical data related to equivalent device, if applicable
   - 5.2. Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable
   - 5.3. Summary of clinical data from other sources, if applicable

5.4. An overall summary of the clinical performance and safety
5.5. Ongoing or planned post-market clinical follow-up

6. Possible diagnostic or therapeutic alternatives

7. Suggested profile and training for users

8. Reference to any harmonised standards and CS applied

9. Revision history

SSCP revision number	**Date issued**	**Change description**	**Revision validated by the Notified Body**
			☐ Yes Validation language: ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
			☐ Yes Validation language: ☐ No

If the SSCP concerns a device for which it is relevant to provide information to patients in lay man's language, the following text can be included and then followed by a "page break":
A summary of the safety and clinical performance of the device, intended for patients, is given below.

Summary of safety and clinical performance
Document revision:
Date issued:

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 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.

1. Device identification and general information
   - Device trade name
   - Manufacturer; name and address

- Basic UDI-DI
- Year when the device was first CE-marked

2. Intended use of the device
   - Intended purpose
   - Indications and intended patient groups
   - Contraindications

3. Device description
   - Device description and material/substances in contact with patient tissues
   - Information about medicinal substances in the device, if any
   - Description of how the device is achieving its intended mode of action
   - Description of accessories, if any

4. 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
   - Remaining risks and undesirable effects
   - Warnings and precautions
   - Summary of any field safety corrective action, (FSCA including FSN) if applicable

5. Summary of clinical evaluation and post-market clinical follow-up
   - Clinical background of the device
   - The clinical evidence for the CE-marking
   - Safety

6. Possible diagnostic or therapeutic alternatives
   When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

   - General description of therapeutic alternatives

7. Suggested training for users