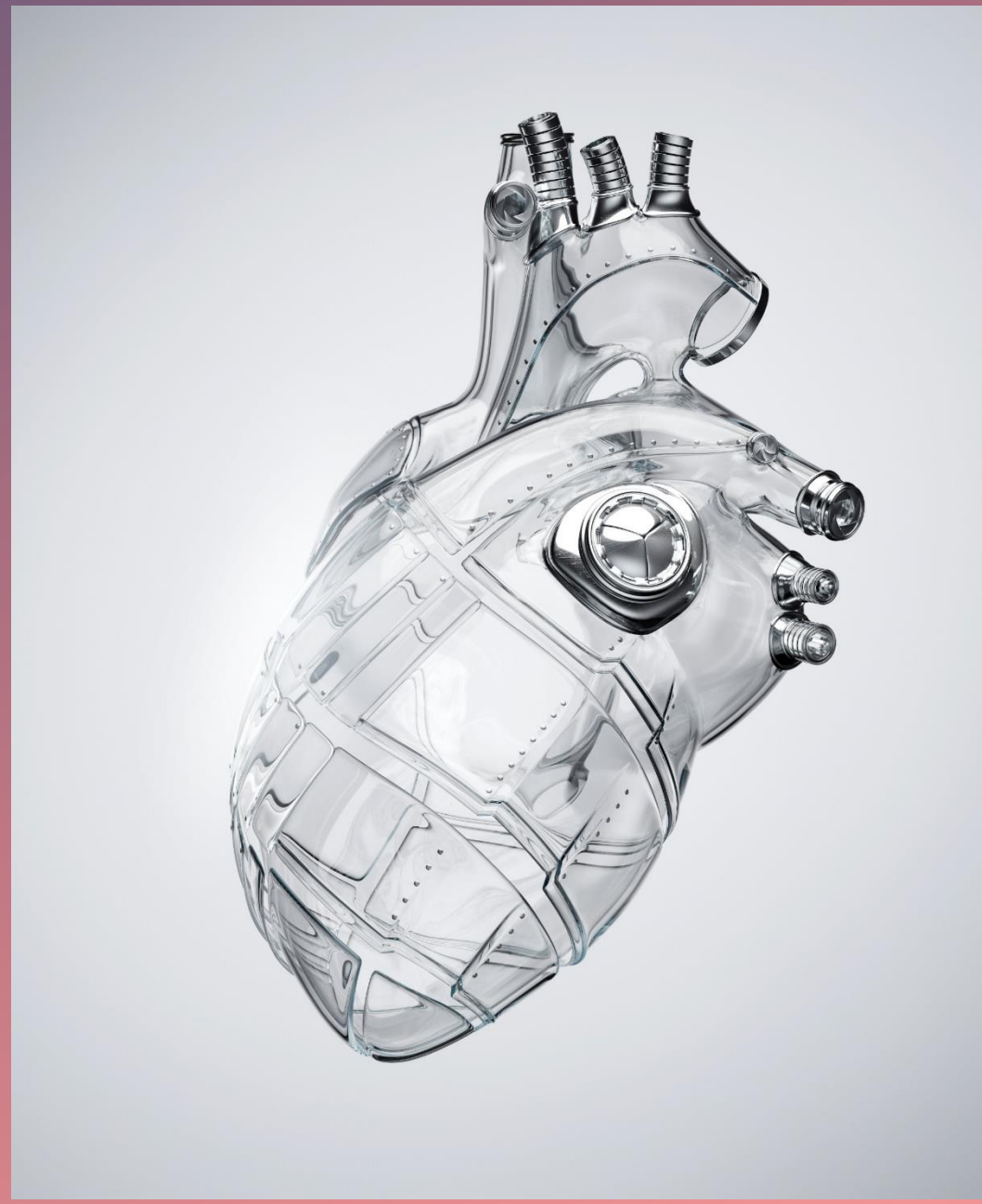
Summary of Safety and Clinical Performance (SSCP)

BSI Clinical Masterclass 2023
Session 5

08th March 2023



Topics covered in the SSCP Session

SSCP Requirements & Purpose
- What is Validation?
- Initial SSCP Validation

SSCP Updates
- Update Schedule
- Submission of SSCP Updates to the Notified Body

SSCP Submission:
- Draft and Final SSCP's
- When & Where to submit SSCP's

A few Pointers:
- Legal Manufacturer (SRN)
- HCP & Patient Sections
- Readability
- Unique Identifier
- Device Nomenclature

Device Groupings
- Multiple Basic-UDI's
- Examples

Link from the IFU to the SSCP

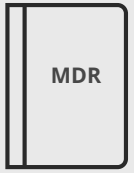
SSCP Requirements & Purpose

- What is Validation?
- Initial SSCP Validation

SSCP – The Requirements

MDR - Article 32(1):

*For **implantable devices and for class III devices**, other than custom-made or investigational devices, **the manufacturer shall draw up a summary of safety and clinical performance***

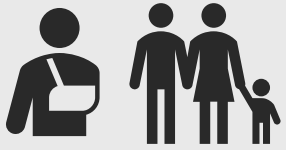


Class III

Implantable Devices

CLASSIFICATION:
SSCP is required for all Class III and all Implantable devices under the MDR.

*The summary of safety and clinical performance shall be written in a way that is clear to the **intended user** and, if relevant, to the **patient** and shall be made available to the **public** via Eudamed.*



TRANSPARENCY:
The information in the SSCP is targeted at the Intended User and the Patient.

*The **draft of the summary of safety and clinical performance shall be part of the documentation** to be submitted to the notified body involved in the conformity assessment pursuant to Article 52 and **shall be validated by that body**. After its validation, the notified body shall upload the summary to Eudamed.*

VALIDATION:
The draft SSCP is included in the Technical Documentation and first validated by the Notified Body during the initial Conformity Assessment process.

EUDAMED

PUBLIC ACCESS
After validation, the Notified Body uploads the SSCP to EUDAMED where it is available to the public

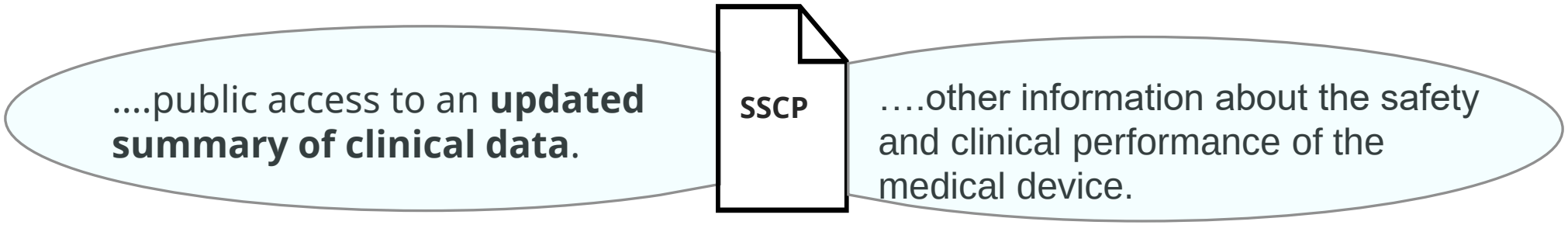
*The manufacturer **shall mention on the label or instructions for use where the summary is available**.*

The Summary of Safety and Clinical Performance can be found here.

IFU or LABEL:
The label or IFU should mention where the summary is available.

SSCP – Purpose

The SSCP is intended to provide.....

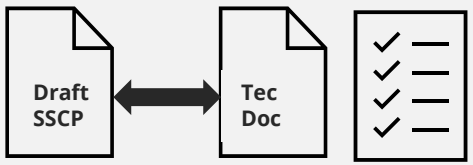


MDR Recital 43: Transparency and adequate access to information, appropriately presented for the intended user, are essential in the public interest, to protect public health, to empower patients and healthcare professionals and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system.

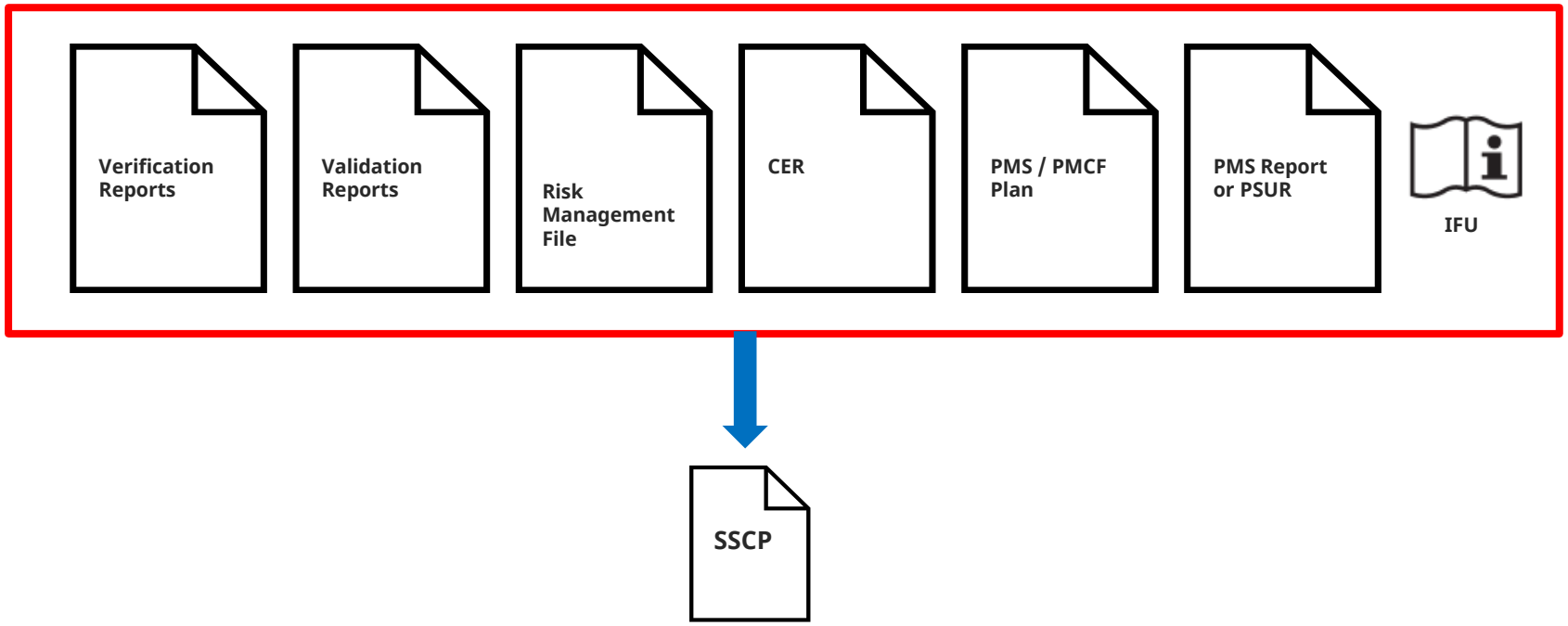
- MDR Recital 43 touches on a fundamental aspect of the MDR – transparency and adequate access to information for patients and healthcare professionals.
- The SSCP is an important source of information for both healthcare professionals and patients.
- SSCP provision is one way in which the preamble in this recital is achieved within the MDR.

SSCP – What is Validation by a Notified Body?

1. The term validate in this context means that the NB should at the end of a conformity assessment ensure the **data in the SSCP has been verified and aligns to the data that has been assessed** within the manufacturer's technical documentation.



Alignment of Safety & Performance Data



The information in the SSCP should be sourced entirely from the Technical Documentation of the device.

SSCP – What is Validation by a Notified Body?

2. The validation step will also check that the **minimum required elements for an SSCP as outlined in Article 32(2) have been included,** along with the **stylistic and readability recommendations within MDCG 2019-9.**

Minimum required content. Written with the target audience in mind.

Article 32 (2) – Summary of Safety & Clinical Performance

2. The summary of safety and clinical performance shall include at least the following aspects:

(a) the identification of the device and the manufacturer, including the Basic UDI-DI and, if already issued, the SRN;

(b) the intended purpose of the device and any indications, contraindications and target populations;

(c) 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;

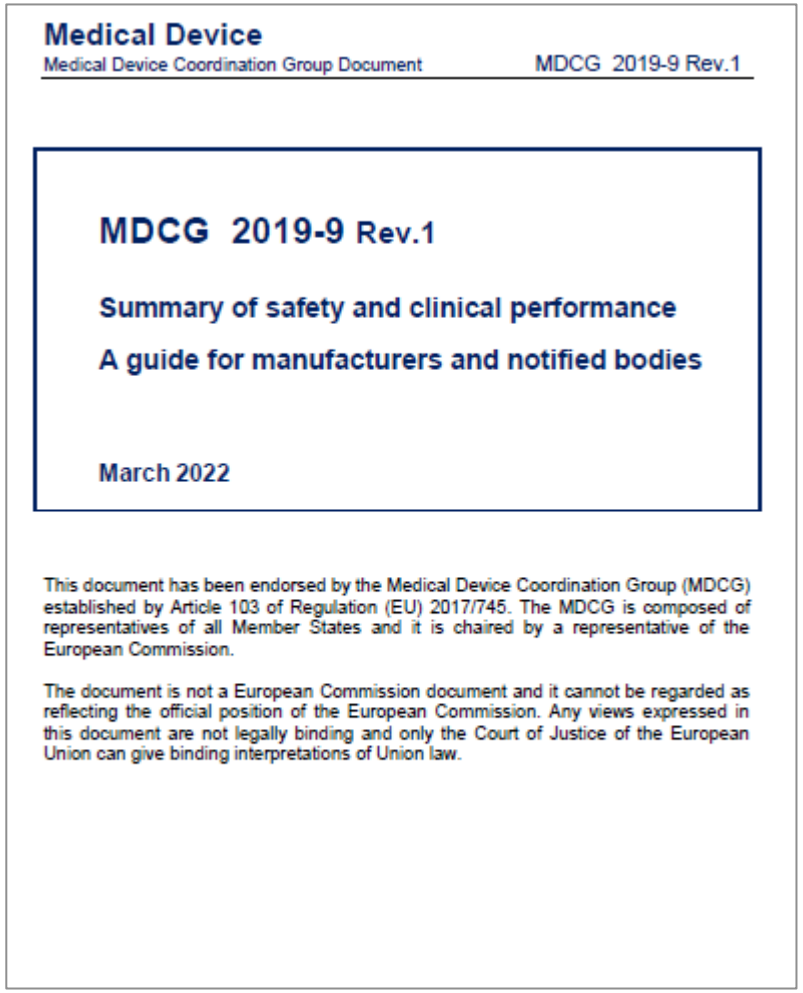
(d) possible diagnostic or therapeutic alternatives;

(e) reference to any harmonised standards and CS applied;

(f) the summary of clinical evaluation as referred to in Annex XIV, and relevant information on post-market clinical follow-up;

(g) suggested profile and training for users;

(h) information on any residual risks and any undesirable effects, warnings and precautions.



Medical Device
Medical Device Coordination Group Document MDCG 2019-9 Rev.1

MDCG 2019-9 Rev.1

Summary of safety and clinical performance

A guide for manufacturers and notified bodies

March 2022

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

MDCG 2019-9 SSCP Guidance – Expected Content

MDCG 2019-9: One of the first guidance documents issued (Aug 2019)

Outlines the minimum required content for the SSCP with guidance on each the required sections.

The Appendix includes a template which manufacturers are recommended to follow

Stylistic recommendations (font size, type, PDF format, simple language) are also provided which is important for the SSCP

BSI's SSCP Validation Checklist is based on the MDCG 2019-9 guidance.

When we conduct SSCP validation, the minimum required elements = the content including stylistic and readability recommendations outlined in the MDCG 2019-9 guidance.

The Initial SSCP Validation Process in BSI

The initial SSCP Validation is conducted by the TS / CES during the Clinical Assessment element of the Technical Documentation review.

As per MDCG 2019-9: *When the NB has assessed that all the required elements 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.*

	R1 Questions	R2 Questions	R3 Questions
Clinical Assessment including draft SSCP Validation		 Clinical Evaluation Specialist (C730-CS)	
Technical Assessment		 Technical Specialist	

The Internal Clinician is responsible for making the decision regarding the adequacy of the Clinical Evidence upon which the SSCP is based.

Clinical Oversight

Internal Clinician

Certificate Recommendation	Decision Making & Certificate Issuance	EUDAMED information uploaded by the NB*
 Scheme Manager	 Panel  MDR Certificate	**Certificate Registration data** – including certificate scope and validity period **SSCP Upload**  Final SSCP

The Final SSCP will * be uploaded to EUDAMED at the end of the Conformity Assessment process at the time of the Certificate Registration.

* This information will be accessible to the Public in EUDAMED once it is fully functional.

SSCP Updates

- Update Schedule

- Submission of SSCP Updates to the Notified Body

SSCP Updates

Remember the SSCP is intended to provide.....

....public access to an **updated summary of clinical data**.

For this reason, in addition to the initial SSCP validation, updates to the SSCP also have to be validated by the Notified Body and made available to the target audience (Intended User & Patient)

SSCP Updates & Validation – Requirements & Guidance

MDR - Article 61 (11)

11. The clinical evaluation and its documentation shall be updated throughout the life cycle of the device concerned with clinical data obtained from the implementation of the manufacturer's PMCF plan in accordance with Part B of Annex XIV and the post-market surveillance plan referred to in Article 84.

*For **class III devices and implantable devices,** the PMCF evaluation report **and, if indicated**, **the summary of safety and clinical performance referred to in Article 32 shall be updated at least annually with such data.***

For Class III & Implantable Devices, the PMCF Evaluation report should be updated at least annually**.**

Linked to this all SSCP's require at least annual updates to incorporate any data which has been obtained from the implementation of the PMCF Plan**.**

MDR - Article 83 (3)d

3. Data gathered by the manufacturer's post-market surveillance system shall in particular be used:

*(d) **to update the summary of safety and clinical performance referred to in Article 32***

Data from PMS shall be used to update the SSCP.

MDR - Article 86

*1. Manufacturers of **class IIb and class III devices shall update the PSUR at least annually.***
*Manufacturers of **class IIa** devices shall update the PSUR when necessary and **at least every two years.***

2. For class III devices or implantable devices, manufacturers shall submit PSURs…..to the notified body involved in the conformity assessment in accordance with Article 52. The notified body shall review the report and add its evaluation to that electronic system with details of any action taken.

- Class III and IIb devices: PSUR is updated at least annually.
- Class IIa devices: PSUR is updated at least every 2 years.
- The NB reviews and evaluates the PSURs for all Class III & Implantable devices.

MDCG 2019-9 Rev 1 Summary of Safety & Clinical Performance

General requirements and recommendations for the SSCP

*The SSCP shall be kept updated in Eudamed. **When the PMCF evaluation report and the periodic safety update report (PSUR) are updated at least annually, the SSCP shall be reviewed and updated 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.*

The Guidance helps put the requirements in Article 61(11) into context:

- When PMCF Reports and PSUR reports are updated at least annually, the SSCP shall be reviewed and updated to ensure that the clinical and safety information in it remains correct and complete.
- When updating the SSCP all sections should be updated to maintain alignment with the current version of the Technical Documentation.

Validation of updates of the SSCP between certification activities

The manufacturer shall submit a PSUR to the NB at least annually, or for class IIa implantable devices at least every two years.
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.

The Guidance also provides some clarity in relation to how SSCP Updates will be validated by Notified Bodies between certification activities:

- **If the SSCP has been updated with new or changed information, the updated SSCP is submitted to the Notified Body when submitting the corresponding PSUR.**
- Whereas the SSCP updates by the manufacturer are required at least annually, submission of the SSCP to the NB is aligned with the PSUR submission timing which is annually with the exception of the IIa Implants where PSUR submissions are required at least every 2 years.

Poll Question

Q: The manufacturer is obligated to keep the SSCP updated. How often should the SSCP be updated?

a. At least annually
b. At least every 2 years
c. It depends on the device classification

Poll Question

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a. **At least annually**
b. **At least every 2 years**
c. **It depends on the device classification**

SSCP Update Schedule

Class III Implantable, Class III, Class IIb Implantable & IIb Non Implantable-Non WET

Initial SSCP Validation conducted as part of the initial Technical Documentation Conformity assessment.

The manufacturer is obligated to keep the SSCP updated. **The SSCP should be updated annually**.

PSURs also require annually updates.

PSURs are submitted annually to the NB for evaluation.

The SSCP is submitted to the NB along with the PSUR **<u>if it includes new or changed information</u>.**

A draft SSCP which has been updated within the previous 12 months is submitted regardless of whether there are new data or conclusions.

- SSCP must be submitted to the NB
- SSCP update required by the manufacturer
- PSUR submission to the NB required

SSCP Update Schedule

Class IIb Implantable WET as per Art 52(4): Sutures, Staples, Dental fillings etc

Technical Documentation is assessed for at least **one representative device per Generic Device Group. At least one draft SSCP shall be validated against relevant documents in the TD** during the initial conformity assessment, prior to issuing the certificate.

SSCPs should be provided for all devices in the Generic Group at the time of the initial Conformity Assessment.

The manufacturer is obligated to keep the SSCP updated. **The SSCP should be updated annually.**

PSURs also require annually updates.

PSURs are submitted annually to the NB for evaluation.

The SSCP is submitted to the NB along with the PSUR **if it includes new or changed information**.

If the SSCP has been previously validated, the NB should validate the updated SSCP against the submitted and evaluated PSUR.

If the SSCP has not previously been validated, the NB may defer the validation until the Technical Documentation is reviewed as per the sampling plan within that certification cycle.

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.

The manufacturer should confirm that the SSCP in EUDAMED is in alignment with the current version of the TD, or provide an updated SSCP where required.

SSCP must be submitted to the NB

SSCP update required by the manufacturer

PSUR submission to the NB required

SSCP Update Schedule

Class IIa Implantable

Technical Documentation is assessed for **at least one representative device for each category of device. At least one draft SSCP shall be validated against relevant documents in the TD** during the initial conformity assessment, prior to issuing the certificate.

SSCPs should be provided for all devices in the category at the time of the initial Conformity Assessment.

The manufacturer is obligated to keep the SSCP updated. **The SSCP should be updated annually.**

PSURs updated at least every 2 years.

PSURs are submitted to the NB for evaluation ever 2 years.

The SSCP is submitted to the NB along with the PSUR **if it includes new or changed information**.

If the SSCP has been previously validated, the NB should validate the updated SSCP against the submitted and evaluated PSUR.

If the SSCP has not previously been validated, the NB may defer the validation until the Technical Documentation is reviewed as per the sampling plan within that certification cycle.

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.

The manufacturer should confirm that the SSCP in EUDAMED is in alignment with the current version of the TD, or provide an updated SSCP where required.

SSCP must be submitted to the NB

SSCP update required by the manufacturer

PSUR submission to the NB required

Submission of SSCP Updates to the Notified Body

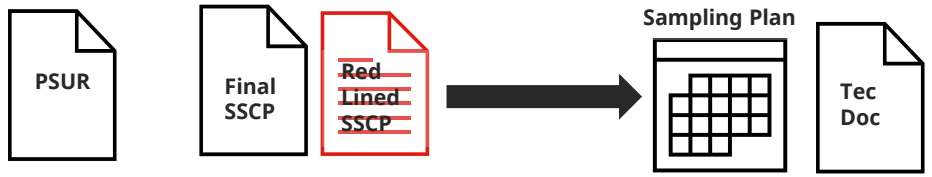
- PMCF Evaluation reports, PSURs and the device Technical Documentation will be updated throughout the lifecycle of the device.
- SSCP's are reviewed and updated at least annually by the manufacturer to maintain alignment with the current version of the Technical Documentation and to ensure that the information in each SSCP's is up to date.
- Whereas the manufacturer can and should continue to revise SSCP's annually and as required throughout the device and certification lifecycle, updated versions should only be submitted to the NB for validation at the time of a certificate change or a scheduled PSUR review.

With the Technical Documentation submitted to the NB to support approval of a certificate change

OR

Annual or Bi-annual NB PSUR Review

At the time of the next scheduled PSUR review



Technical Documentation assessed by Sampling
If the SSCP provided with a PSUR has not previously been validated (IIa Implantable & IIb Implantable WET as per Art 52(4)), the NB may defer the SSCP validation until the Technical Documentation is reviewed as per the sampling plan within that certification cycle.

Administrative or Editorial Updates to the SSCP

MDCG 2019-9

Validation of the initial SSCP by the NB
The NB shall upload the SSCP validated ***in conjunction with an initial conformity assessment*** *at the same time that it uploads the issued certificate.*

Validation of updates of the SSCP between certification activities
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.***

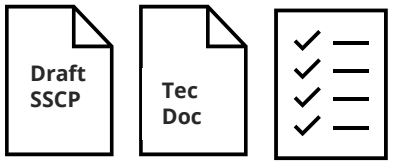
- The Notified Body will validate the original SSCP during the initial conformity assessment.
- The manufacturer is obligated to keep the SSCP updated, with at least annual SSCP updates to incorporate clinical data obtained from the implementation of the PMS & PMCF Plan.
- **The NB is not required to validate every SSCP update or version released by the manufacturer.**
- Validation of SSCP updates is aligned with schedule for PSUR Reviews. Where there is new /changed information in the SSCP obtained through the PMS System, the NB will validate the updates at the time of the next scheduled PSUR review (PSUR reviews occur annually with the exception of for IIa Implants which are every 2 years)
- Editorial or administrative changes to the SSCP can be made by the manufacturer at any time without NB approval (assuming the change is non-significant).
- **Non-significant administrative and editorial changes to an SSCP should only ever be validated at the time of a PSUR review OR at the time of a Supplementary Conformity Assessment to support the approval of a certificate change.**

Summary – Options available for SSCP Validation

Initial SSCP Validation

All SSCP's will be first validated at the time of the Initial Technical Documentation assessment.

For the Implantable Devices which are on a QMS certificate (IIa Implantable and IIb WET) at least one SSCP will be validated alongside the Technical Documentation selected as representative of the product group during the initial assessment. All other devices SSCPs should be provided but the validation will take place when the related Technical Documentation is sampled over the certification cycle.



SSCP Updates

Option 1

At the time of the next scheduled PSUR review

SSCP Validations at the time of the PSUR Evaluation need to be within the scope of the information contained in the PSUR. Editorial updates can also be validated along with the PSUR.

Option 2

With the Technical Documentation submitted to the NB to support approval of a certificate change

If there are any updates to the SSCP that are outside the scope of the PSUR (excluding editorial changes) then Technical Documentation will need to be submitted to allow the validation checks to be conducted

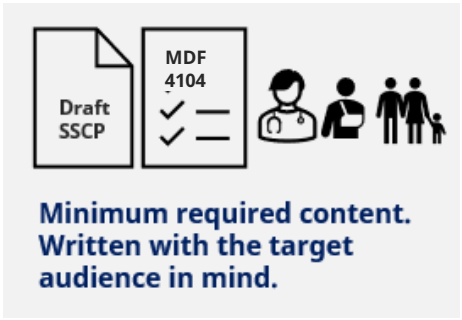
Remember: The SSCP Validation check verifies that the content of the SSCP aligns with data that has been assessed within the manufacturers Technical Documentation. The source Technical Documentation always needs to be assessed before the corresponding information in the SSCP can be validated.

SSCP Submission:

- Draft and Final SSCP’s
- When to submit a Final SSCP
- Where to Submit

Draft and Final SSCP's – What's the Difference?

SSCP Validation is conducted on a draft SSCP with the validation documented on the BSI Form MDF4104



As per MDCG 2019-9**:** *When the NB has assessed that all the required elements 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.*

- The draft SSCP is provided to the Notified Body for validation purposes during an initial Conformity Assessment or Certification Change Review.
- The content of the draft SSCP often needs to be revised as a result of questions raised by the reviewer during the Conformity Assessment process.

The final SSCP is the SSCP which has been released in the manufacturers document control system and is the document which will be provided to the Intended User & Patient

- The final document should be a stand-alone document provided in PDF format.
- It should not have red-lines, draft or confidentiality markings as this will be the copy of the SSCP which is made available to the Intended User, Patient or Public.
- The content of the final document should be identical to the content validated by BSI using the draft SSCP.
- As per MDCG 2019-9 "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 SSCP's for class IIa implantable or some IIb implantable devices; whether the SSCP revision has been validated yet or not by the NB"

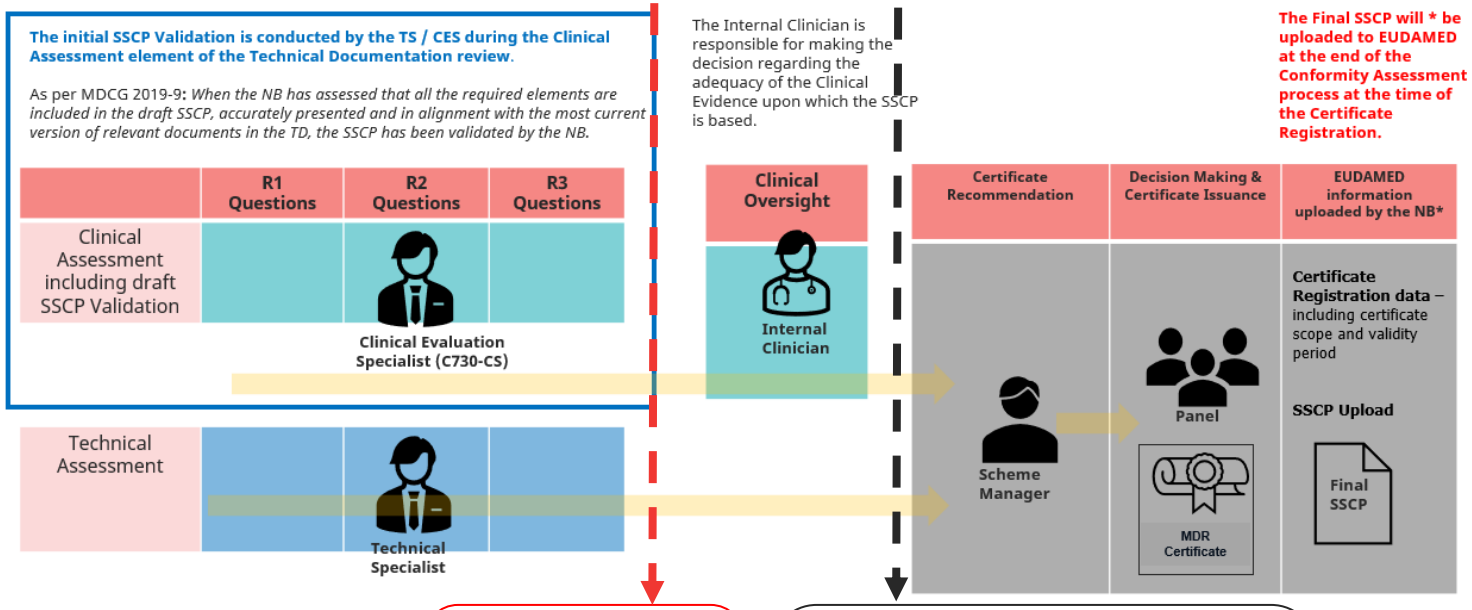
9. Revision History

SSCP Revision Number	Date Issued	Change Description	Revision Validated by Notified Body
1	15th October 2021	Initial release	☒ Yes Validation Language: English ☐ No

When is the Final SSCP Required?

The Final SSCP will * be uploaded to EUDAMED at the end of the Conformity Assessment process at the time of the Certificate Registration.

Once the SSCP Validation is complete on MDF4104, the BSI reviewer should always request a final copy of the SSCP from the manufacturer.
The final SSCP must be on file with BSI before the Conformity Assessment is complete to ensure its available for upload to EUDAMED at the end of the Conformity Assessment Process

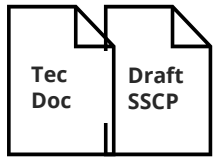


The final SSCP will always be requested once the SSCP Validation is complete.

Where Clinical Oversight is required for SSCP validation, it is possible to delay the provision of the final SSCP until the IC is has completed their assessment. The final SSCP must be in place before the CO Job can be completed.

SSCP Upload to the Notified Body

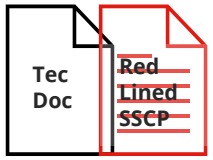
Initial MDR **Conformity Assessment**



A draft SSCP should be included in the Technical Documentation which is uploaded via the BSI Document Upload Portal

Once the Notified Body completes the SSCP Validation a final copy of the SSCP will be requested from the manufacturer.
The final SSCP should also be uploaded via the BSI Document Upload Portal

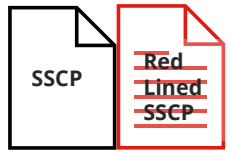
Supplementary **Conformity Assessment** (Certificate Change)



When submitting Technical Documentation supporting a change approval, a red-lined SSCP should be included in the Technical Documentation which highlights all changes made to the SSCP since a final version was last provided to the NB along with any updates related to the proposed change. The Supplementary Technical Documentation is uploaded via the BSI Document Upload Portal

Once the Notified Body completes the Conformity Assessment to support the proposed change and validates the updates to the SSCP a final copy of the SSCP will be requested from the manufacturer.
The final SSCP should also be uploaded via the BSI Document Upload Portal

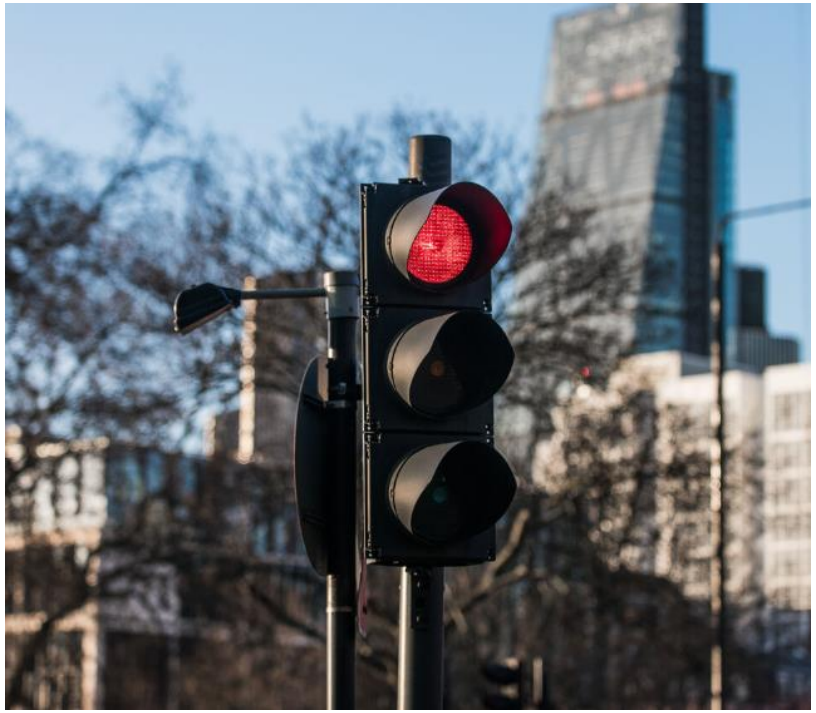
SSCP Submission along with next the scheduled PSUR



If the SSCP has been updated with new / changed information, the manufacturer should upload the current version of the SSCP to the BSI Vigilance Portal at the same time as the PSUR.

A red-lined SSCP should also be uploaded to highlight all changes made within the SSCP since a final version was last provided to the NB.

SSCP Translations



- We are not accepting SSCP translations at present as EUDAMED functionality is not available for us to upload them.
- The expectation is that manufacturers hold the SSCP translations and can make them available to the public upon request.
- As soon as BSI has the ability to upload the translated SSCP's to EUDAMED we will contact our manufacturers asking for the translations to be submitted.
- The BSI Vigilance Portal will be used in the future to receive SSCP translations and collect the associated metadata.

In the interim period, please do not submit translated SSCP's to BSI.

Poll Question

Q: A manufacturer is submitting their first PSUR to BSI for a scheduled review. The PSUR updates have resulted in updates to the SSCP. Where should the PSUR and SSCP be uploaded for review?

a. **BSI Document Upload Portal**
b. **BSI Vigilance Portal**
c. **I have no idea. I'm just going to email the documents to my Scheme Manager**

Poll Question

Q: A manufacturer is submitting their first PSUR to BSI for a scheduled review. The PSUR updates have resulted in updates to the SSCP. Where should the PSUR and SSCP be uploaded for review?

a. BSI Document Submission Portal
b. BSI Vigilance Portal
c. I have no idea. I'm just going to email the documents to my Scheme Manager

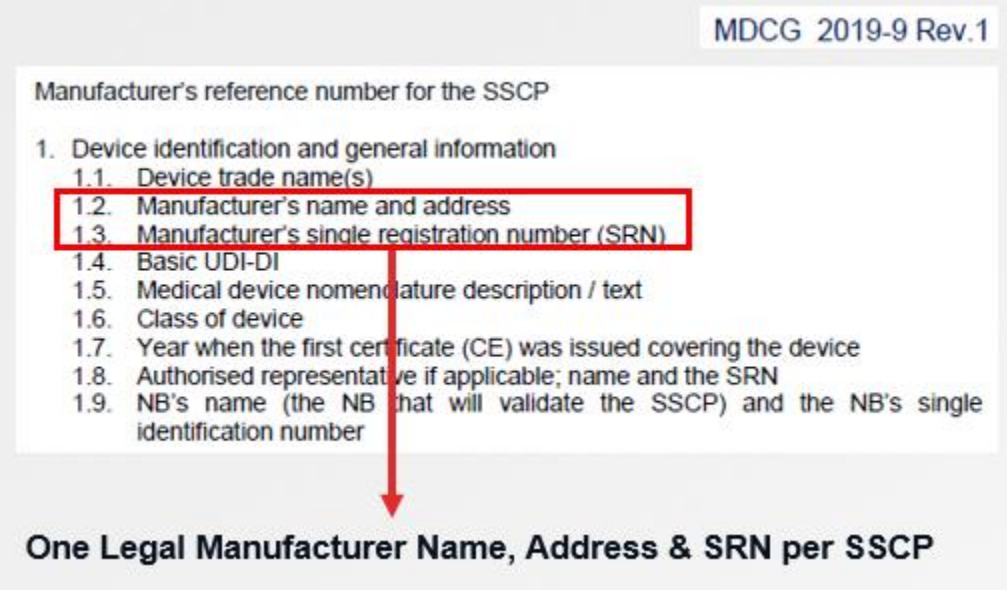
A few Pointers:

- Legal Manufacturer (SRN)
- HCP & Patient Sections
- Readability
- Unique Identifier
- Device Nomenclature

SSCP – Legal Manufacturer & SRN

Where a single device is placed on the market by multiple Legal Manufacturer's, each Legal Manufacture will need to produce their own individual SSCP for that device which includes their legal manufacturers name, address and SRN.

The SSCP is similar to a DOC & Certificate in that it is unique to each Legal Manufacturer.



SSCP – Intended User & Patient Sections

HCP Part

Intended User

Health Care Professional

The SSCP should **ALWAYS** have a section which is written for the Intended User or Health Care Professional.

Patient Part

Patient

The SSCP will include a second section which is written specifically for the patient **ONLY if it is considered "relevant"**.

Relevant:

SSCP's where a patient section is considered relevant include:

- **Implantable devices for which patients will be given Implant Cards**. This includes all Implantable devices with the exception of those identified as well-established technologies and listed within Article 52(4) i.e., sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors.
- **Class III devices that are intended to be used directly by patients**.
- **Devices listed in Annex XVI without an Intended Medical Purpose** which are either Class III or Implantable devices.

Not Relevant:

For all other devices requiring an SSCP, the manufacturer should consider whether it is relevant to provide information specifically for the patient for that device.

Where a Patient SSCP is not considered relevant, the manufacturer should provide a justification in the Technical Documentation for not including a patient section within the SSCP. This justification should focus on the actual device and why the safety and clinical performance information is not deemed to be relevant or of interest to the patient.

Consider & Justify

SSCP – Intended User & Patient Sections - Readability

MDCG 2019-9 Readability:
Both (parts) *should be clear and provide information at an appropriate depth to reflect the healthcare professionals' and the patients' different levels of knowledge.*

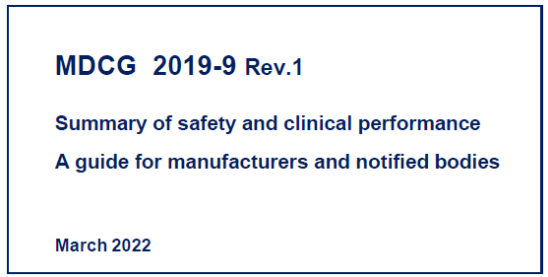
*It is **<u>recommended</u>** that the readability of the part of the SSCP intended for patients is assessed for example by a **test given to lay persons**.*

*The manufacturer **<u>may use a method it finds adequate</u>** for the readability test to confirm that the SSCP is written in a way that is clear to the patient **e.g. software**.*

MDCG 2019-9 makes reference to an EU published document titled 'Summaries of Clinical Trial Results for Laypersons' which refers to Flesch-Kincaid score as a method to assess readability.

- When BSI conducts SSCP validation and is considering the readability of the patient section of the SSCP, we are open to accepting any solution which demonstrates that the information is written in a way which will be clear to the patient.
- Either a test given to lay persons OR readability tests conducted by software methods including the Flesch-Kincaid Scoring system are acceptable methods to demonstrate readability.
- Regardless of the method used, we always need to be satisfied that medical terms are simplified and that the patient information is communicated in a simple, clear way.

SSCP Identifier (Reference Number)



General requirements and recommendations for the SSCP

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.

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

- This paragraph was added to Rev 1 of the SSCP Guidance issued in March 2022.
- Having a **unique identifier for each SSCP, which remains unchanged for its lifetime is critical** to ensure that SSCP's can be uploaded and updated within EUDAMED.
- The identifier itself can consist of any combination of letters, numbers or other characters to refer to the document (eg SSCP2023) and the revision (eg ver or rev) fields.
- Regardless of the identifier used, it must remain unchanged on all future versions of the SSCP, with the only change allowed being to the actual physical revision number.
- Translations of each SSCP must be assigned the exact same identifier and revision number as the master SSCP.

SSCP Identifier (Reference Number) – EUDAMED

SSCP details

Notified Body identification

Notified Body number: 2797

Name: BSI Group The Netherlands B.V.

Country: Netherlands

SS(C)P identification

SS(C)P reference number:	SSCP2023
SS(C)P revision number:	18
Uploaded from:	Certificate registration
Date issued:	2023-01-01

The SSCP issue date should include a **Date**, Month and Year NOT Month/Year for the purposes of EUDAMED upload.

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

In this example the unique SSCP identifier or reference number is "SSCP2023". Every version of this SSCP, including translations must use the identifier "SSCP2023" to allow upload to EUDAMED.

The version number prefix used must also be maintained for the lifetime of the SSCP, for example V2 to V3 NOT V2 to Version 3.

SSCP – Medical Device Nomenclature

MDCG 2019-9 Rev.1

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

Medical Devices

DG Health and Food Safety
Directorate Health systems, medical products and innovation
Unit Medical Devices

January 2020

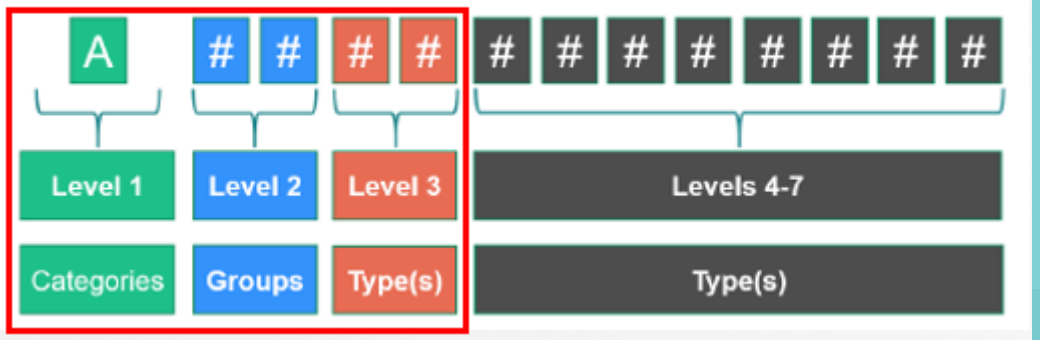
The European Medical Device Nomenclature (EMDN)

The European Medical Device Nomenclature (EMDN) will be the nomenclature of use by manufacturers when registering their medical devices in the EUDAMED database.

SSCP - Section 1.5

- Use of EMDN nomenclature is a requirement under Article 26.
- The EMDN code should be provided by the manufacturer in the SSCP.
- EMDN nomenclature is available online and as a downloadable list from the European Commission website ttps://ec.europa.eu/tools/eudamed/#/screen/search-device
- When referencing EMDN within the Technical Documentation, in general the most granular term available should be used.
- When validating the SSCP, BSI will record the EMDN Code on the validation checklist / form to at least 4 digits.

EMDN Structure

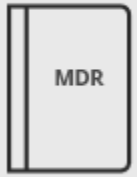


Device Groupings

Device Groupings within the SSCP

MDR - Article 32(1):

*For **implantable devices and for class III devices**, other than custom-made or investigational devices, **the manufacturer shall draw up a summary of safety and clinical performance***



Class III

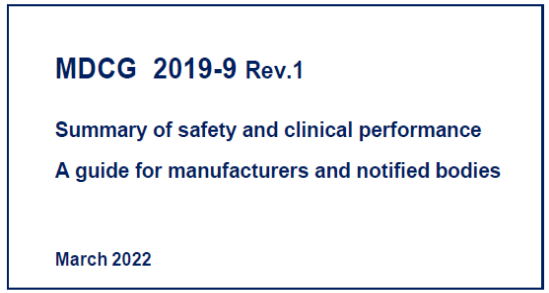
Implantable Devices

CLASSIFICATION:
SSCP is required for all Class III and all Implantable devices under the MDR.

The SSCP is required to be drawn up for all Class III and Implantable devices.
The SSCP is a device specific document, drawn up at the device level.

Guidance on SSCP Device Groupings & Basic-UDI

Section 3.1....
*In Eudamed, the **SSCP is associated to one unique Basic UDI-DI**. All UDIDIs / devices associated to this Basic UDI-DI will be seen as having the same SSCP (a UDI-DI / device must always be associated with one and only one Basic UDI-DI).*



Section 3.1....
*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 same SSCP (a UDI-DI / device must always be associated with one and only one Basic UDI-DI).*

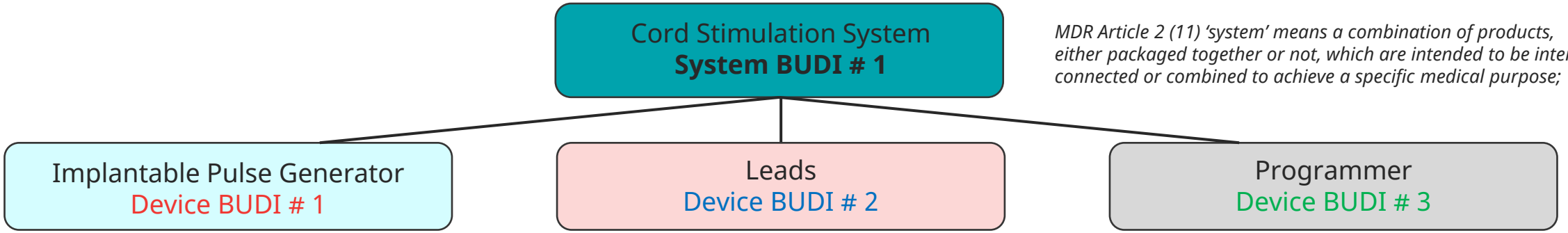
MDCG 2019-9 Rev.1 changes	
section 3.1	clarification on the association of the SSCP with the Basic UDI-DI in EUDAMED
general requirements and template	addition of a manufacturer reference number

- The original SSCP Guidance indicated that each SSCP was to be associated with a unique Basic-UDI.
- This was not practical; the current version of the SSCP guidance clarifies that each SSCP can be associated with either one or multiple Basic UDI-DI's.

So although the SSCP is written at a device level it is (SOMETIMES!) possible to group multiple devices or BUDI's in a single SSCP.

Example 1

SSCP for a System



MDR Article 2 (11) 'system' means a combination of products, either packaged together or not, which are intended to be inter-connected or combined to achieve a specific medical purpose;

MDCG 2019-9 Rev.1

Summary of safety and clinical performance

A guide for manufacturers and notified bodies

March 2022

Section 3.1....
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.*

- A single MDR Product Certificate is issued for the Cord Stimulation System.
- This single Product certificate includes and lists the three devices (Implantable Pulse Generator, Leads and the Programmer) which are used together as Cord Stimulation System along with the three associated Device BUDI's.

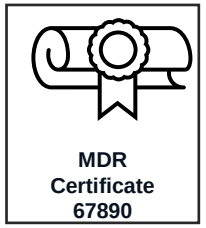
- A single SSCP is drafted for the Cord Stimulation System which includes safety and clinical performance data for all three devices when used together.
- Section 1.4 of the SSCP should identify the Basic UDI for the System – in this example it should be the **System BUDI # 1.**
- Section 3.1 of the SSCP should describe the overall system AND all of the devices associated with that system including the Device Basic-UDI's (Device BUDI # 1, Device BUDI #2 and Device BUDI #3)

Example 2

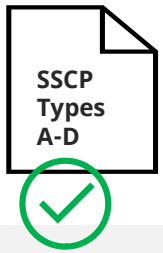
SSCP for Multiple BUDI's (One Device Group - Four different Designs)

Device Group- Dental Abutments used to connect a dental implant & the crown	Classification	Intended Purpose	Design & Manufacturing Characteristics	BUDI
Abutment to Implant Type A	Class IIb Implantable WET	Dental Implants are intended to replace missing teeth. The Abutments are connecting elements that are placed onto the implants to allow fixation of the crown.	Design A	Device BUDI # 1
Abutment to Implant Type B			Design B	Device BUDI # 2
Abutment to Implant Type C			Design C	Device BUDI # 3
Abutment to Implant Type D			Design D	Device BUDI # 4
	Same	Same	Different	Four Device BUDI's

BUDI – identification number used to administrative purposes to connect devices with the same:
- Classification
- Intended purpose
- Essential Design & Manufacturing Characteristics



- There are four types of device in the device group.
- Based on the type of device and the fact each design is used in exactly the same way, in this example it makes sense to assess all four devices together during one Technical Documentation assessment.
- Once the overall initial Conformity Assessment including the Technical Documentation assessment is complete, a QMS certificate can be issued with the product family "Dental Abutments " in the scope.



- A single SSCP is drafted for the Dental Abutments which includes safety and clinical performance data for all four device types.
- The information in the SSCP can be validated for all four device designs once the Conformity Assessment assessing all four devices is complete.

Example 3

SSCP for Multiple BUDI's (One Device Group - Three different Designs)

Class IIb Implantable WET as per Art 52(4): Sutures, Staples, Dental fillings etc

Technical Documentation is assessed for at least **one representative device per Generic Device Group. At least one draft SSCP shall be validated against relevant documents in the TD** during the initial conformity assessment, prior to issuing the certificate.

SSCPs should be provided for all devices in the Generic Group at the time of the initial Conformity Assessment.

MDR Article 2(7):
"generic device group' means a set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;

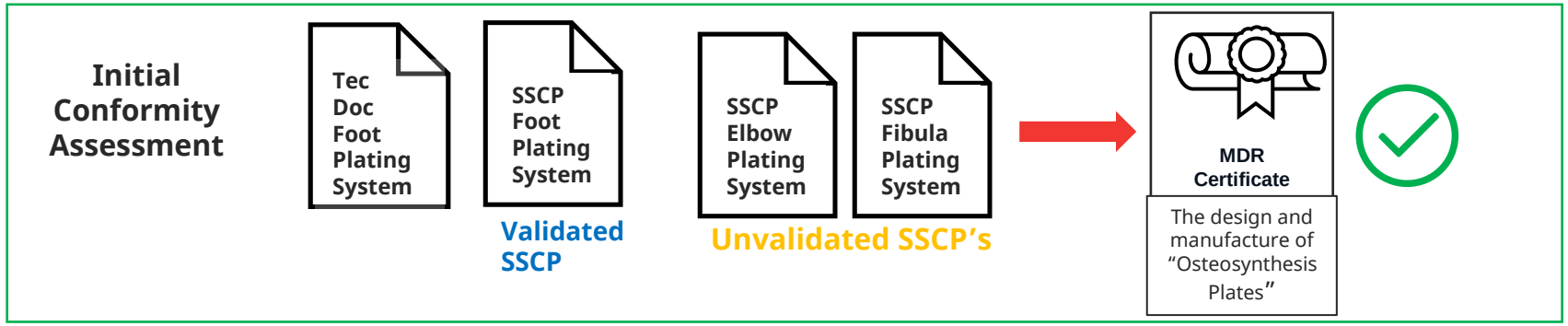
MDR Article 52(4):

4. Manufacturers of class IIb devices, other than custom-made or investigational devices, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, and including an assessment of the technical documentation as specified in Section 4 of that Annex of at least one representative device per generic device group.

Device Group - Osteosynthesis Plate	Classification	Intended Purpose	Design & Manufacturing Characteristics	BUDI
Foot Plating System	Class IIb Implantable WET	Fixation of Fractures in the Foot	Foot Design	Device BUDI # 1
Elbow Fracture Plating System		Fixation of Fractures in the Elbow	Elbow Design	Device BUDI # 2
Distal Fibula Plating System		Fixation of Fractures in the Fibula	Fibula Design	Device BUDI # 3

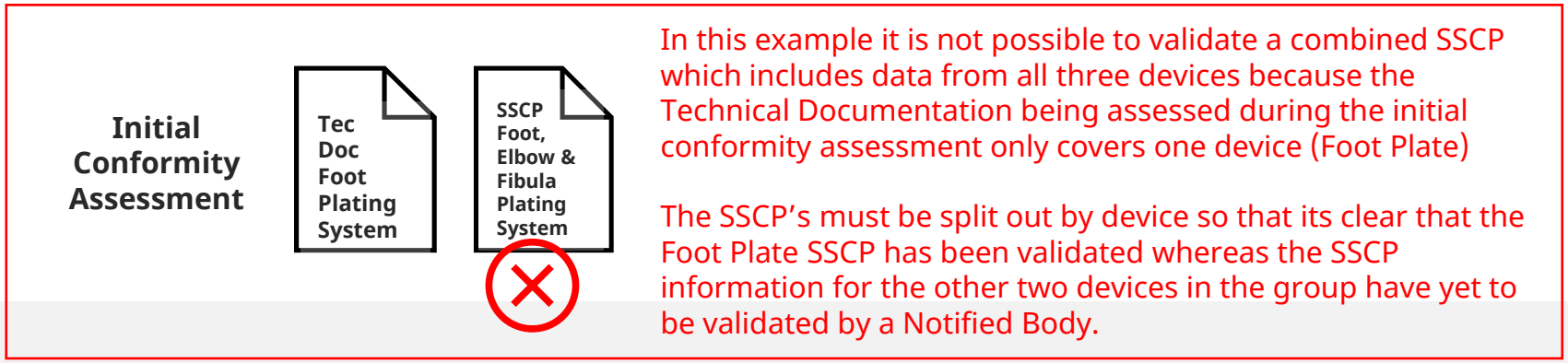
- There are three types of device in the Generic Device Group.
- Although the three devices can be grouped together generically, because each is used within a different anatomical location, each would be expected to have different Technical Files with different sets of supporting data.
- It would be difficult to assess the Foot, Elbow and Fibula plates together within a single Technical File assessment (you could…but it would effectively be 3 reviews rather than one!)
- Instead at least one representative device is chosen from the device group for Technical Documentation assessment during the Initial Assessment – in this case the Foot Plating System is selected for initial assessment purposes.

SSCP for Multiple BUDI's (IIb Implantable WET – 1 Generic Device Group, 3 Devices)



Once the overall initial Conformity Assessment including the Technical Documentation assessment for the Foot Plating System is complete:

- The SSCP for the Foot Plating System can be validated based on the Technical Documentation assessed for the Foot Plate device.
- The SSCPs for all other devices in the group need to be provided during the Initial Assessment but can not be validated as the corresponding Technical Documentation has yet to be sampled.
- The Initial Conformity Assessment supports the issuance of a QMS certificate with the product family "Osteosynthesis Plates " in the scope.
- The unvalidated SSCP's will be validated when the Technical Documentation for the related devices are sampled as part of the surveillance cycle over the certification cycle.



In this example it is not possible to validate a combined SSCP which includes data from all three devices because the Technical Documentation being assessed during the initial conformity assessment only covers one device (Foot Plate)

The SSCP's must be split out by device so that its clear that the Foot Plate SSCP has been validated whereas the SSCP information for the other two devices in the group have yet to be validated by a Notified Body.

Key Take-Away - SSCP's associated with multiple Basic-UDI's

It is possible to include multiple devices or Basic-UDI's in a single SSCP. However care is needed as:

- It is NOT possible to partially validate SSCP content.
- The Conformity Assessment must be complete for all devices included in each SSCP before the SSCP Validation can be finalised.

Also keep in mind the purpose of the SSCP – Transparency for the Intended Users & Patients. As you add more devices and pages to each SSCP there is the possibility that the document loses the elements of transparency and clarity which are essential.

Cord Stimulation System
System BUDI # 1

Implantable Pulse Generator
Device BUDI # 1

Leads
Device BUDI # 2

Programmer
Device BUDI # 3

Clinical Evaluation Specialist (C730-CS)

	R1 Questions	R2 Questions	R3 Questions
Clinical Conformity Assessment including draft SSCP Validation			

	R1 Questions	R2 Questions	R3 Questions
Clinical Conformity Assessment including draft SSCP Validation			

	R1 Questions	R2 Questions	R3 Questions
Clinical Conformity Assessment including draft SSCP Validation			

SSCP System

Internal Clinician

Clinical Oversight

Certificate Recommendation	Decision Making & Certificate Issuance	EUDAMED information uploaded by the NB*
Scheme Manager	Panel MDR Certificate	**Certificate Registration data** – including certificate scope and validity period **SSCP Upload** Final SSCP

Link from the IFU to the SSCP

IFU & Link to SSCP – Requirements & Guidance

MDR - Article 32(1):

……

The summary of safety and clinical performance shall be written in a way that is clear to the intended user and, if relevant, to the patient and shall be made available to the public via Eudamed.

……

The manufacturer shall mention on the label or instructions for use where the summary is available.

The label or IFU is required to mention where the summary (SSCP) is available.

MDR – Annex I, GSPR 23.4 d

23.4. Information in the instructions for use
The instructions for use shall contain *all of the following particulars:*

…..

(d) where applicable, ***links to the summary of safety and clinical performance referred to in Article 32;***

GSPR 23.4 is a little more specific: The IFU (as opposed to the label or IFU in Article 32) is required to link to the SSCP.

MDCG 2019-9 Rev 1 Summary of Safety & Clinical Performance.

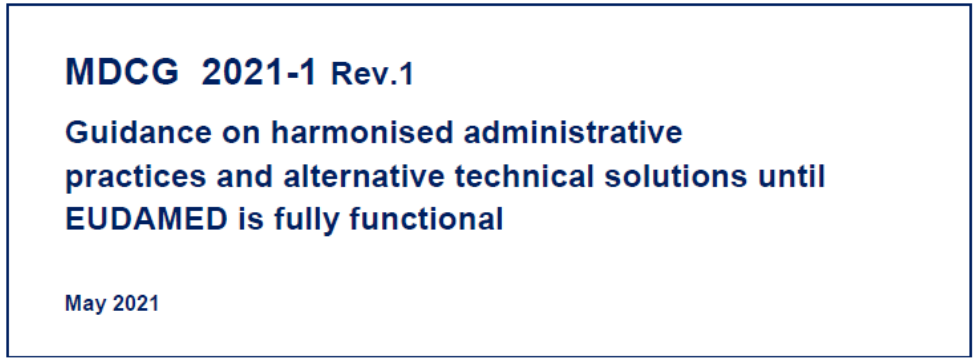
The IFU shall contain all that is needed to directly find the SSCP in Eudamed*. The following applies to the IFU.*

- ***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.*

The SSCP Guidance:

- Highlights that the IFU should contain enough information to enable the SSCP to be found within EUDAMED.
- Indicates that the IFU is required to state that the SSCP is available on EUDAMED.
- It recommends the inclusion of the EUDAMED URL within the IFU.
- It suggests the use of Basic-UDI as a solution to link the device to the SCCP, but also gives manufacturers the option to use alternative methods to identify the SSCP.

What does BSI expect with respect to the IFU link to SSCP?



MDCG 2021-1 Rev.1

Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional

May 2021

Article 32

The SSCP shall be made available to the public upon request without undue delay or the manufacturer shall specify where it is made available to the public.

As soon as the functionality is available in Eudamed, the system may be used for the upload of the SSCP even before the notice of full functionality of Eudamed has been published.

- The intention of GSPR 23.4 (d) is to ensure that the IFU contains enough information to find the SSCP in EUDAMED.
- Regardless of EUDAMED functionality, it is the manufacturers responsibility to ensure SSCP's are indeed accessible to the intended audience (Users & Patients) to meet the intent of the MDR.
- Once EUDAMED is functional the requirement in 23.4(d) will be met by the provision of a link to EUDAMED.
- Until EUDAMED is functional, manufacturers must be able to demonstrate that they have an alternative solution in place to provide SSCP's to interested stake-holders without undue delay.
- BSI is open to any solution which achieves this (As per the MDCG 2021-1 Guidance: SSCP available on request OR specify where it is available)
- Our Technical Reviewers will need to be satisfied that there is a satisfactory solution in place for SSCP provision without undue delay. Our QMS assessors will audit the process during initial and surveillance QMS audits.

Best Practice Guidance Document

Best Practice Guidance Document

- The best practice guidance (BPG) document will provide you with a comprehensive guide on how best to prepare your clinical documentation specifically the CEP, CER, PMCF Plans and SSCP.
- The BPG will also provide information on the clinical evaluation assessment process at BSI.
- The BPG is going through the final stages of development and hope for it to be available as part of a clinical toolkit in April 2023.
- During these webinars we have received a significant number of questions. We will be producing a 'Top 10 FAQ' for each webinar. This will provide 50 questions with answers and will be part of the clinical toolkit.
- Thank you for all your continued support, we hope you have found the masterclass helpful.

PSUR Webinar

Webinar to be delivered on March 21st 09:00 & 16:00 GMT

- This webinar is critical to understand the process for submitting PSURs to BSI and when you should submit additional documentation (including SSCPs).

- The webinar will explain BSI expectations in relation to the amount of data required in the PSUR and the review process and expected timelines.

- A client communication will follow on this topic in the coming weeks.

- Please register for the webinar here: Register Here.

End slide