MDCG 2022-9 / Rev.1

Summary of safety and performance Template

April 2024

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.

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MDCG 2022-9 Rev.1 changes	
Introduction	Clarification on when the SSP should be made available to patients, elimination of footnote 3
Footnote 2	In line with MDCG 2019-9 rev.2
Section 1A	“Indication whether it is a device for near-patient testing and/or a companion” moved from point 1.7 to point 2.3
Section 1A, 1B and 2	”Intended use of the device” was replaced by ”Intended purpose and other indications” in point 2.

Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (the IVDR) requires that the manufacturer shall draw up a summary of safety and performance (SSP) for class C and D devices, other than devices for performance studies. The SSP shall be validated by a notified body (NB) and made available to the public via the European database on medical devices (Eudamed).[1]

Text elements in *italic* in the template are general information proposed to be included in the SSP document.

The SSP should include information dedicated to the intended user, and if relevant, the patient. The SSP shall be kept updated[2] in Eudamed.

If the device is not intended for self-testing, the SSP should be dedicated to the professional user. Furthermore, where the manufacturer considers it relevant to provide an SSP for patients, a part dedicated to patients and written in a way that is clear to lay persons should be added. The SSP template for devices not intended for self-testing is presented in Section 1.

If the device is intended for self-testing, the SSP should be written in a way that is clear to the patients/lay persons, for instance taking into consideration the age of the targeted population. The SSP template for devices intended for self-testing is presented in Section 2.

Section 1 – SSP Template for devices not intended for self-testing

All the fields/chapters of information have to be filled in even for cases that are not applicable. In this case “not applicable” should be entered.

Summary of Safety and Performance

This Summary of Safety and Performance (SSP) is intended to provide public access to an up-to-date summary of the main aspects of the safety and performance of the device.

The SSP 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.

In Section 1.A, the following should be added:

The following information is intended for professional users.

If the SSP includes a part intended for patients/lay persons, the following should be

[1] IVDR, Article 29 (1)

[2] The manufacturer should verify whether updates of its PMPF evaluation report (Article 56(6)) and the periodic safety update report (PSUR, Article 81 (1)) require also an update of the SSP.

added:

Following this information there is a summary intended for patients/lay persons (please see Section 1B).

A. Summary of safety and performance for professional users

Document revision:

Date issued:

Manufacturer's reference number for the SSP:

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[3,]
   1.5. European Medical Device Nomenclature (EMDN) description / text
   1.6. Risk class of device
   1.7. Year when the device was first CE-marked under Regulation (EU) 2017/746 covering the device
   1.8. Authorised representative if applicable; name and the SRN
   1.9. NB's name (the NB that will validate the SSP) and the NB's single identification number

2. Intended purpose and other indications
   2.1. Intended purpose (elements in Annex II 1.1 (c))
   2.2. Indication(s) and target population(s)
   2.3. Indication whether it is a device for near-patient testing and/or a companion diagnostic
   2.4. Limitations and/or contra-indications (e.g. relevant interferences, cross-reactions)

3. Device description
   3.1. Description of the device, including the conditions to use the device (e.g. laboratory, near-patient testing)
   3.2. In case the device is a kit, description of the components (including regulatory status of components, for example, IVDs, medical devices and any Basic UDI-DIs)
   3.3. A reference to previous generation(s) or variants if such exists, and a description of the differences
   3.4. Description of any accessories which are intended to be used in combination with the device
   3.5. Description of any other devices and products which are intended to be used in combination with the device

4. Reference to any harmonised standards and CS applied

[3] In Eudamed, the SSP is associated to one or multiple Basic UDI-DI(s).

5. Risks and warnings
   5.1. Residual risks and undesirable effects
   5.2. Warnings and precautions
   5.3. Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN), if applicable

6. Summaryof performance evaluation and post-market performance follow-up(PMPF)[4,5]
   6.1. Summary of scientific validity of the device
   6.2. Summary of performance data from the equivalent device[6], if applicable
   6.3. Summary of performance data from conducted studies of the device prior to CE-marking[7]
   6.4. Summary of performance data from other sources, if applicable
   6.5. An overall summary of the performance and safety
   6.6. Ongoing or planned post-market performance follow-up

7. Metrological traceability of assigned values
   7.1. Explanation of the unit of measurement, if applicable
   7.2. Identification of applied reference materials and/or reference measurement procedures of higher order used by the manufacturer for the calibration of the device

8. Suggested profile and training for users

9. Revision history

SSP revision number	Date issued	Change description	Revision validated by the Notified Body
			☐ Yes Validation language: ☐ No (only applicable for class C (IVDR, Article 48 (7)) for which the SSP is not yet validated by the NB)[8]

[4] More detail is expected compared to the information provided in the Instructions for Use.
[5] Specifically, in the case of a companion diagnostic a summary of performance data that shows the device isessential for the safe and effective use of the medicinal product should be included.
[6] IVDR Annex IX, 4.5 and Annex X, 3(d)
[7] Specifically, for a companion diagnostic co-developed with a medicinal product, the concerned medicinal product study and device version used in that study should be referenced. If different device versions have beenused in the clinical development program performed, concordance studies should be described
[8] For class C devices, a draft SSP should be submitted to the NB involved in the conformity assessment as part ofthe application documents. The draft SSP should be validated by the NB. In the circumstance that more than one device is covered by the relevant certificate, at least one draft SSP should be validated against relevant documents in the technical documentation during the initial conformity assessment, prior to issuing the certificate. Draft SSPs that are not validated at the initial conformity assessment should be validated against relevant documents in the technical documentation at least once during the period of validity of the certificate.

			☐ Yes Validation language: ☐ No

If the SSP concerns a device for which it is relevant to provide information to patients in lay person language, the following text can be included and then followed by a page break:

A summary of the safety and performance of the device, intended for patients, is given below.

B. Summary of safety and performance for patients/lay persons

Document revision:

Date issued:

This Summary of Safety and Performance (SSP) is intended to provide public access to an updated summary of the main aspects of the safety and performance of the device **not intended for self-testing**. *The information presented below is intended for patients or lay persons. A more extensive summary of the safety and performance prepared for healthcare professionals is found in the first part of this document, section 1.A.*

The SSP is not intended to give general advice on the diagnosis and/or 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. The SSP is not intended to replace the Instructions For Use to provide information on the safe use of the device

1. Device identification and general information
   1.1. Device trade name
   1.2. Manufacturer; name and address
   1.3. Basic UDI-DI
   1.4. Risk class of device
   1.5. Year when the device was first CE-marked under Regulation (EU) 2017/746

2. Intended purpose and other indications
   2.1. Intended purpose (including intended patient groups)
   2.2. Indications

2.3. Contra-indications and/or limitations

3. Device description
   3.1. General device description
   3.2. Description of how the device is achieving its intended purpose
   3.3. Description of accessories or other devices/equipment needed to use the device in question, if any

4. Risks and warnings

   Contact your healthcare professional if you are concerned about the use of the device or about the results. This document is not intended to replace a consultation with your healthcare professional, if needed.

   4.1. How potential risks have been controlled or managed
   4.2. Remaining risks and undesirable effects
   4.3. Warnings and precautions
   4.4. Summary of any field safety corrective actions including field safety notices, if applicable

5. Summary of performance evaluation and post-market performance follow-up
   5.1. Summary of scientific validity of the device
   5.2. Summary of performance data from studies of the device prior to CE-marking, and if applicable from equivalent device and other sources
   5.3. Ongoing or planned post-market performance follow-up

6. Suggested profile and training for users

Section 2 – SSP Template for self-testing devices

All the fields/chapters of information have to be filled in even for cases that are not applicable. In this case “not applicable” should be entered.

Summary of Safety and Performance

This Summary of Safety and Performance (SSP) is intended to provide public access to an updated summary of the main aspects of the safety and performance of the device.

The SSP 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.

Document revision:

Date issued:

The information presented below is intended for patients or lay persons.

The SSP is not intended to give general advice on the diagnosis and/or 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.

Manufacturer’s reference number for the SSP:

1. Device identification and general information
   - 1.1. Device trade name
   - 1.2. Manufacturer; name and address
   - 1.3. Manufacturer’s single registration number (SRN)
   - 1.4. Basic UDI-DI[4]
   - 1.5. European Medical Device Nomenclature (EMDN) description / text
   - 1.6. Risk class of device
   - 1.7. Year when the device was first CE-marked under Regulation (EU) 2017/746
   - 1.8. Authorised representative if applicable; name and the SRN
   - 1.9. NB’s name (the NB that will validate the SSP) and the NB’s single identification number

2. Intended purpose and other indications
   - 2.1. Intended purpose (including intended patient groups)
   - 2.2. Indications
   - 2.3. Contra-indications and/or limitations

3. Device description
   - 3.1. General device description (including reference to previous generation(s) or

variant(s) if such exist, and a description of the differences)

3.2. In case the device is a kit, description of the components (including regulatory status of components, for example, IVDs, medical devices and any Basic UDI-DIs)

3.3. Description of how the device is achieving its intended purpose

3.4. Description of accessories and/or other devices/equipment needed to be used in combination with the device in question, if any

4. Reference to any harmonised standards and common specification applied

5. Risks and warnings

Contact your healthcare professional if you are concerned about the use of the device or about the results. This document is not intended to replace a consultation with your healthcare professional, if needed.

5.1. How potential risks have been controlled or managed

5.2. Remaining risks and undesirable effects

5.3. Warnings and precautions

5.4. Summary of any field safety corrective actions including field safety notices, if applicable

6. Summary of performance evaluation and post-market performance follow-up

6.1. Summary of scientific validity of the device

6.2. Summary of performance data from studies of the device prior to CE-marking, and if applicable from equivalent device and other sources

6.3. An overall summary of the performance and safety

6.4. Ongoing or planned post-market performance follow-up

7. Metrological traceability of assigned values

7.1. Explanation of the unit of measurement, if applicable

7.2. Identification of applied reference materials and/or reference measurement procedures of higher order used by the manufacturer for the calibration of the device

8. Suggested profile and training for users, if applicable

9. Revision history

SSP revision number	Date issued	Change description	Revision validated by the Notified Body

			☐ Yes Validation language: ☐ No[8]
			☐ Yes Validation language: ☐ No