MDCG 2022-9

Summary of safety and performance Template

May 2022

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 yoursituation.

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 use of the device
   - 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**
			☐ **Yes** **Validation language:** ☐ **No**