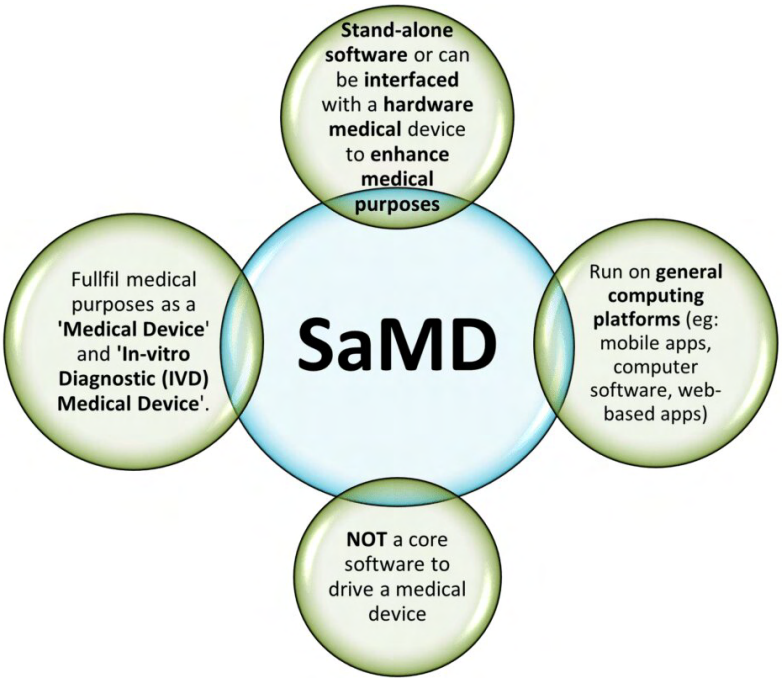
SOFTWARE AS A MEDICAL DEVICE CLASSIFICATION - US vs EU

After reading this factsheet you should:

- Understand US and EU classification of software as a medical device.
- Understand the difference between US and EU classification of software as a medical device.

Introduction

Software that is used for medical purposes but is not a physical component of a medical device is referred to as "software as a medical device" (SaMD). The US Food and Drug Administration (FDA) and the European Union (EU) have established SaMD classification and regulatory frameworks. This factsheet provides a summary of SaMD categorization in the US and the EU.



How are SaMD classified in the EU?

In the US the FDA defines SaMD as "software that is intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device". If your software does not meet this definition, then the following regulation options apply:

- No FDA regulation: If the software does not meet the SaMD definition and does not pose risk to the patient then it is not subject to FDA regulations e.g., patient reference app.
- FDA discretion: If the software does not meet the SaMD definition but may be of minor risk to the patient then it is FDA discretion whether regulatory control is necessary e.g., health related reminders.

The FDA categorises SaMD into different classes based on the level of risk they pose to the patient. SaMD falls into one of three categories: Class I, Class II, or Class III, with Class III devices carrying the most risk. More info on device classification in US here.

- Class I: Low risk devices with little potential for harm to patients. These devices require general controls but do not require special controls. E.g., software that tracks information about physical activity, such as heart rate, steps taken, and distance travelled.
- Class II: Moderate risk devices. These devices require special controls. Manufacturers are required to submit a 510(k)-pre-market notification proving that their product is substantially equivalent to one that is legally marketed. E.g., automated software for processing radiological images.
- Class III: High risk devices that support or sustain human life or pose risks to the patient. These devices require premarket approval. E.g., software that collects data from an implantable device and enables the user to maintain track of their health condition.

More information on FDA SaMD can be found here. More information on SaMD framework for risk categorisation can be found on the FDA website here.

How are SaMD classified in the EU?

In the European Union (EU), The International Medical Device Regulators Forum (IMDRF) defines SaMD as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device".

The Medical Device Regulation (MDR) 2017/745 (Annex VIII) outlines the regulatory framework for medical devices in the EU, which includes SaMD. The EU categorises SaMD into four different classes based on the level of risk they pose to the patient.

- Class I: Low-risk devices that don't interact with patients directly. These devices have general safety and performance requirements (Paragraph 3, Article 61), and the manufacturer can self-certify them. An example of this is a mobile app to track general wellness.
- Class IIa: Moderate risk devices that have a direct or indirect impact on the patient's health but bear low risk. Conformity assessment by a notified body is required. An example software that monitors a patient's vital signs.
- Class IIb: Moderate risk devices that have a direct or indirect impact on the patient's health but bear a higher risk than class IIa. Conformity assessment by a notified body is required. An example is a smartphone app designed to evaluate a user's heartbeat, find any anomalies, and alert a doctor when necessary.
- Class III: High risk devices that are invasive or have high potential to cause harm to patients. Conformity assessment by a notified body is required as well as clinical evaluation and post market clinical follow up (Annex XIV Part A). An example is software intended to provide diagnosis through image evaluation for treatment options in acute stroke patients.

Software is the focus of Annex VIII rule 11 of EU MDR 2017/745 however should be reviewed in the context of other rules such as rule 9 and 10 to ensure accurate classification. Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 can be found here.

What are the differences between US and EU SaMD classification?

1. Number of classes: FDA has three classes for SaMD whereas EU MDR has four classes. The EU MDR had two separate classes for moderate risk SaMD.
2. Conformity: In the US, premarket notifications (510k) are evaluated by the FDA and clearance is granted. In the EU, class IIa, IIb and III must undergo conformity evaluations by notified bodies, which are independent organisations chosen by EU member states.
3. Clinical evaluation: For higher-risk devices (Class IIb and III), the regulatory framework in the EU emphasises the value of clinical evaluation. To verify the safety and performance claims of the device the manufacturer must provide clinical data.