



**Software as a Medical
Device (SaMD)
by the FDA**



Introduction

As digital technologies continue to transform healthcare, software has become a critical component across a wide range of medical and non-medical applications.

In this context, software related to medical devices is categorized into three distinct types:

- **Software in a Medical Device:** integral to the function of the hardware.
- **Software used in the manufacture or maintenance of medical devices.**
- **Software as a Medical Device (SaMD):** software that performs medical functions independently of a hardware device.

This presentation will focus primarily on SaMD, highlighting its definitions, regulatory considerations, and its growing impact on modern healthcare delivery.

SaMD Regulators

To support innovation and ensure patient safety, global regulators recognized the need for a unified approach to Software as a Medical Device (SaMD).

The **International Medical Device Regulators Forum (IMDRF)**, led by agencies like the FDA, created a working group in 2013 to develop global guidance on:

- Defining SaMD Risk-based categorization
- Quality management systems
- Clinical evaluation standards

This collaborative effort promotes safe, effective, and timely access to SaMD worldwide.

What is Software as a Medical Device?

Software as a Medical Device (SaMD) refers to standalone software **used for medical purposes**, functioning independently of traditional medical hardware and increasingly integrated across various digital platforms.



Important Considerations

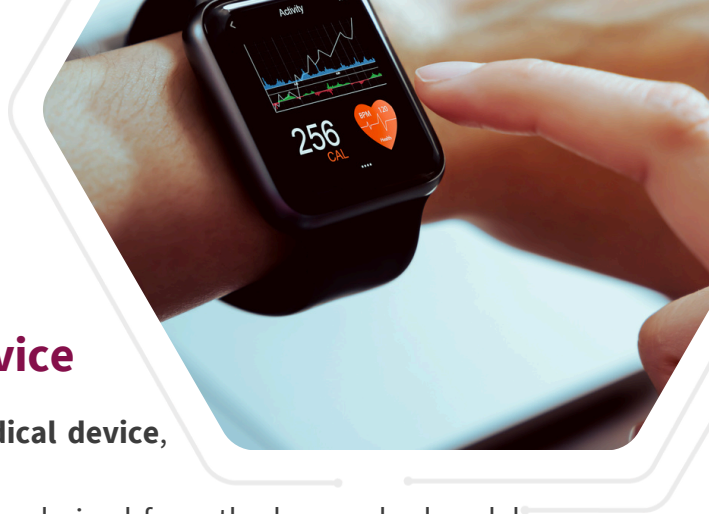
- SaMD is **considered a medical device** and may also include software intended for in-vitro diagnostic (IVD) purposes
- SaMD is capable of operating on general-purpose computing platforms
- Software is not considered SaMD if its primary intended purpose is to drive, control, or influence the operation of a hardware medical device
- SaMD may be used in combination with other products, including medical devices, for example, as a module integrated into a broader system
- SaMD can interface with various other technologies, including hardware medical devices, other SaMD solutions, and general-purpose software platforms
- Mobile apps that meet the definition above are considered SaMD

Medical Device Definition

Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, **software**, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- *Diagnosis, prevention, monitoring, treatment or alleviation of disease.*
- *Diagnosis, monitoring, treatment, alleviation of or compensation for an injury.*
- *Investigation, replacement, modification, or support of the anatomy or of a physiological process.*
- *Supporting or sustaining life.*
- *Control of conception.*
- *Disinfection of medical devices.*
- *Providing information by means of in vitro examination of specimens derived from the human body.*

Does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.



In Vitro Diagnostic (IVD) medical device

In Vitro Diagnostic (IVD) medical device' means a **medical device**, whether used alone or in combination, **intended by the** manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for **diagnostic, monitoring or compatibility** purposes.

Additional considerations for SaMD

SaMD may also:

- Provide means and suggestions for mitigation of a disease.
- Provide information for determining compatibility, detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.
- Be an aid to diagnosis, screening, monitoring, determination of predisposition; prognosis, prediction, determination of physiological status.

Additional considerations for SaMD

For SaMD the “intended use / intended purpose” is the objective **intent of the manufacturer regarding the use of a product**, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

The intended use reflects the manufacturer's objective for the SaMD, based on documentation, labeling, and even sales or marketing materials.

A SaMD manufacturer is any person or entity responsible for the design and/or production of the software, whether done directly or by others on their behalf. They **hold legal responsibility for regulatory compliance**.

SaMD Intended Use / Purpose examples

Examples of Intended Use / Intended Purpose for SaMD include:

- *Cardiac Monitoring App*: Intended to continuously monitor heart rate and detect arrhythmias in adult patients using wearable sensors.
- *Diabetes Management Software*: Designed to support the self-management of diabetes by providing insulin dose calculations based on blood glucose levels and carbohydrate intake.



- *Radiology Image Analysis Tool*: Intended to assist radiologists in detecting lung nodules on CT scans as a decision-support tool.
- *Mental Health Assessment App*: Used to screen for symptoms of depression and anxiety through user responses and behavioral data.
- *Ophthalmology Diagnostic Software*: Developed to analyze retinal images and identify signs of diabetic retinopathy for early referral to a specialist.

SaMD Categorization

Key Principles for SaMD Risk Categorization

- Categorization depends on a **clear, complete** SaMD definition.
- Risk level is based on the significance of the information provided and the healthcare situation it addresses.
- If SaMD applies to multiple conditions, it is classified under **the highest applicable risk** category.
- Any lifecycle changes that affect the SaMD definition require **re-evaluation** of its category.
- **SaMD is categorized independently**, even when integrated with other software or devices.
- Four risk categories (I–IV), with Category IV representing the highest potential impact on patient or public health.

SaMD Categories

State of Healthcare situation or condition	Significance of information provided by SaMD to healthcare decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I



Criteria for Determining SaMD Category

- *Criteria for Category IV*
 - SaMD that provides information to treat or diagnose a disease or conditions in a **critical situation or condition** is a Category IV and is considered to be of very **high impact**.
- *Criteria for Category III*
 - SaMD that provides information to treat or diagnose a disease or conditions in a **serious situation or condition** is a Category III and is considered to be of **high impact**.
 - SaMD that provides information to drive clinical management of a disease or conditions in a **critical situation or condition** is a Category III and is considered to be of **high impact**.
- *Criteria for Category II*
 - SaMD that provides information to treat or diagnose a disease or conditions in a nonserious situation or condition is a Category II and is considered to be of **medium impact**.
 - SaMD that provides information to drive clinical management of a disease or conditions in a **serious situation or condition** is a Category II and is considered to be of **medium impact**.
 - SaMD that provides information to inform clinical management for a disease or conditions in a **critical situation or condition** is a Category II and is considered to be of **medium impact**.
- *Criteria for Category I*
 - SaMD that provides information to drive clinical management of a disease or conditions in a **non-serious situation or condition** is a Category I and is considered to be of **low impact**.
 - SaMD that provides information to inform clinical management for a disease or conditions in a **serious situation or condition** is a Category I and is considered to be of **low impact**.
 - SaMD that provides information to inform clinical management for a disease or conditions in a **non-serious situation or condition** is a Category I and is considered to be of **low impact**.



Reference Guidelines

Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations: <https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf>

Software as a Medical Device (SaMD): Application of Quality Management System: <https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-151002-samd-qms.pdf>

Software as a Medical Device (SaMD): Clinical Evaluation Guidance for Industry and Food and Drug Administration Staff: <https://www.fda.gov/media/100714/download>

Software as a Medical Device (SaMD): Key Definitions; IMDRF SaMD Working Group

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