

Hardian Health



Module 3: How are medical devices classified?



Outline

How are medical devices classified?

This talk will cover:

- Different classifications of devices including examples
- Software as a Medical Device (SaMD)
- Accessories & EU MDR Rule 11

SaMD, SiMD, MDSW and PEMS

SaMD: Software as a Medical Device. Intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.

SiMD: Software in a Medical Device. Incorporated that is typically incorporated into a physical medical device to control its performance or provide specific functions.

MDSW: Medical Device Software. Intended to be used (alone or in combination) for any of the purposes described in the definition of a “medical device” as per EU Medical Device Regulations.

PEMS: Programmable Electrical Medical Systems.

Risk Classification

Significance of information provided by the medical device software to a healthcare situation related to diagnosis/therapy

State of healthcare situation or patient condition

	High <i>Treat or diagnose</i>	Medium <i>Drives clinical management</i>	Low <i>Informs clinical management</i>
Critical situation or patient condition	Class III Medical Device	Class IIb Medical Device	Class IIa Medical Device
Serious situation or patient condition	Class IIb Medical Device	Class IIa Medical Device	Class IIa Medical Device
Non-serious situation or patient condition	Class IIa Medical Device	Class IIa Medical Device	Class IIa Medical Device

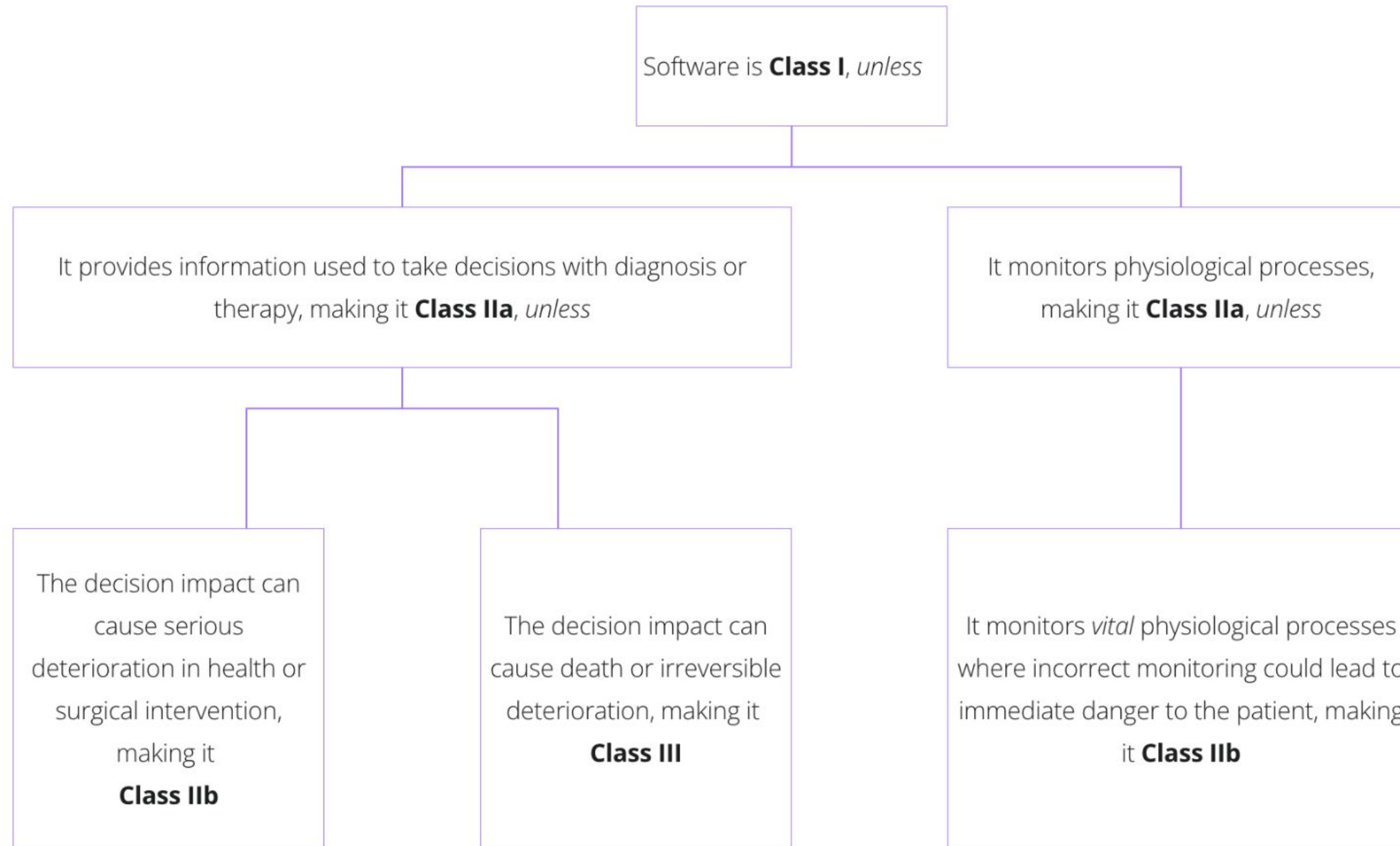
Medical devices under UK MDR 2002 and EU MDR fall into 4 different risk classifications:

- **Class I**
- **Class IIa**
- **Class IIb**
- **Class III**

Most SaMD under EU MDR fall under **Class IIa** at minimum.

Class I software can self-certify, but higher classes require a notified/approved body audit

EU MDR Rule 11



What is PEMS?

Programmable Electrical Medical System which is often combined with an AIaMD/SaMD device as means of data collection, imaging etc

Is there a physical element to your device **e.g. powered data collection tool?**

- Even if you buy in the physical part of your SaMD from another manufacturer, if your name is on the packaging and it is to be used in conjunction with your product you are the **legal manufacturer** therefore take responsibility in its regulatory compliance

What additional requirements are there for a PEMS?

- Electrical and mechanical safety testing, Electromagnetic compatibility and compliance to standards such as EN 60601-1 Medical Electrical Equipment, Biocompatibility, RF testing *where applicable* etc.

Examples of Devices

Traditional examples: pacemakers, defibrillators, stents, valves etc.

Modern SaMD examples: chest X-Ray triage software platform, physiotherapy app, an image processing app which is used to detect pneumonia, cognitive behavioral therapy software, depression treatment app

Modern Hardware examples: surgical Robots, smart contact lenses, Apple watch (arrhythmia detection app)

Accessories

An accessory is not a medical device itself but is intended by its manufacturer to be used with one or more specific medical devices.

Its purpose is to enable or assist the medical device(s) to function as intended.

Accessories shall not act by **pharmacological**, **immunological**, or **metabolic** means as medical devices do.

Example: A software application designed to process and display data from a blood glucose monitor, enabling the monitor to be used effectively by providing necessary data interpretation.

Summary

Key points discussed

- a. Depending on how your device is meant to function, it could be SaMD, SiMD, MDSW, PEMS, or a combination.
- b. Under EU MDR Rule 11 most SaMD is Class IIa or above.
- c. Some SaMD may have a physical element (PEMS) to them of which also needs to be regulated.
- d. Accessories to medical devices are intended to enable a medical device to function, but are not devices themselves.

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