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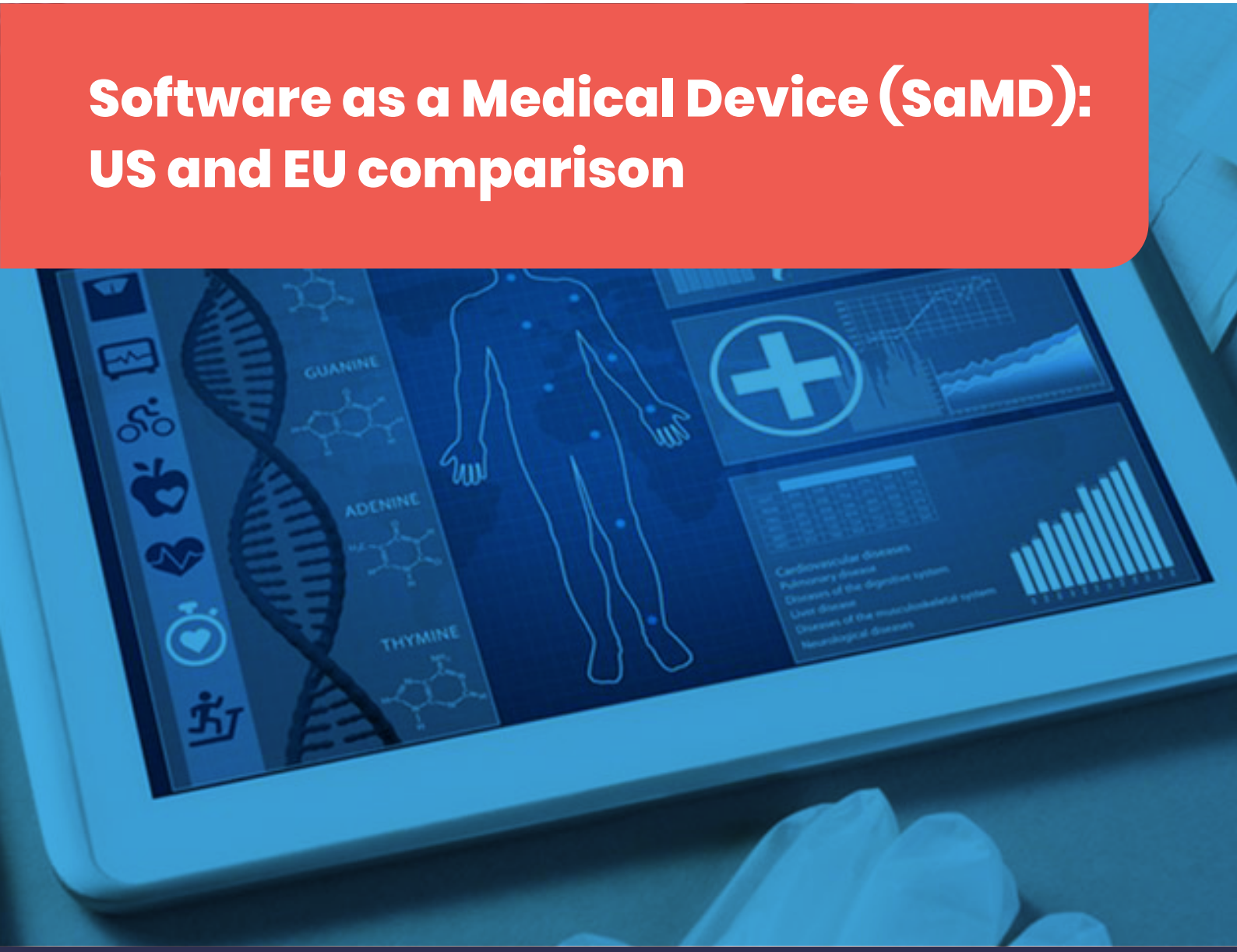
# Software as a Medical Device (SaMD): US and EU comparison

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The International Medical Device Regulators Forum (IMDRF) aims to accelerate international medical device regulatory convergence. It comprises representatives from the medical device regulatory authorities of Australia, Brazil, Canada, China, the EU, Japan, the Russian Federation, Singapore, South Korea and the US. Through the IMDRF, regulators reached consensus on what software is considered a medical device. Regulators call it 'software as a medical device' (SaMD). As SaMD might be regulated in one country but not in another, this is an important consideration for manufacturers' go-to-market strategies and for the availability of SaMD across the world. This paper provides a comparison of how SaMD is regulated in the US and in the EU.

## Software as a Medical Device

The 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'. Software can run on general-purpose IT equipment in 'the cloud' but also on the computing platform of a hardware medical device and still be SaMD. When the hardware medical device needs the software to achieve its intended medical purpose - for example because it drives the hardware or fulfils a purpose claimed for the hardware device - then the software is not SaMD but part of the medical device in the regulatory meaning of the term. For example, consider software for automatic nerve detection intended to run on the computing platform of an ultrasound device. A manufacturer can place such software on the market as SaMD or as part of the ultrasound device, depending on whether the manufacturer wants to assign the nerve detection claim to the ultrasound device or just to the software. Software that does not fulfil a medical purpose on its own, on the other hand, is not SaMD. For example, software intended to solely drive an ultrasound transducer can be placed on the market as an integral part of the ultrasound device or as an accessory of the ultrasound device. Furthermore, few additional important notes are mentioned below:

- SaMD is a medical device and includes in-vitro diagnostic medical devices
- SaMD can run on general purpose (non-medical) computing platforms
- Software is not SaMD if its intended purpose is to drive a hardware medical device
- SaMD may be used in combination with other products including medical devices
- SaMD may interface to other medical devices, including hardware medical devices, other SaMD software, and general purpose software
- Mobile apps that meet the definition are considered SaMD

If the software doesn't fit the above criteria, it is not subject to FDA regulations in the US, in the EU's Medical Device Regulation (MDR), or in the EU's in Vitro Diagnostic Regulation (IVDR). But if it does qualify as SaMD, here's where differences begin to emerge by market.

## Placement on the market

Software can be qualified and placed on the market as:

- A medical device or in vitro diagnostic (IVD) medical device
- An accessory for a medical device or for an IVD medical device (accessories by definition do not fulfill a medical purpose on their own)
- A part or a component of a medical device, IVD medical device or Annex XVI device (Annex XVI devices have no medical purpose but are in scope of the EU Medical Device Regulation (MDR)

If the software is none of the above, it is not subject to the EU MDR, the EU In Vitro Diagnostic Regulation (EU IVDR) or FDA regulations, unless it is placed on the EU market as part of a system – that is a

combination of products, either packaged together or not, that are intended to be interconnected or combined or to achieve a specific medical purpose, in which case it is subject to the EU MDR. Connectivity alone is not sufficient for it to be considered a system, because there is a third condition: the system must be placed on the market as one unit – for example it is sold under a single sales catalogue number.

EU MDR and EU IVDR Article 6 imply that software not placed on the European market might still have to comply with the EU MDR if offered, directly or through intermediaries, to a person established in the EU. Think of software offered as a download or as a service through web portals and application interfaces. If such software operates on servers based outside the EU, then such software might nevertheless be subject to the EU MDR or EU IVDR if it is accessible through, for example, website subscription to a person residing in the EU. Two years after publication of the EU MDR, the FDA clarified that, in the US, software as a service might be regulated as a medical device.

## Regulatory Requirements: FDA

The FDA has published multiple guidance documents regarding the regulation of software, including SaMD. Some types of software are regulated as medical devices, whereas other types of software are not regulated, and a third type of software is subject to 'enforcement discretion' – technically, the product is regulated but the FDA will not actively pursue enforcement unless there is a reason to.

## Regulatory Requirements: EU

The EU uses the term Medical Device Software (MDSW) instead of SaMD. It defines MDSW as software that is intended to be used, alone or in combination, for a purpose as specified in the definition of 'medical device' in the MDR or IVDR.

The EU uses a different term because:

1. It does not regulate SaMD with functionality that is limited to storage, communication, lossless compression, or simple searching or that is intended for the benefit of populations rather than individuals and
2. Contrary to SaMD, software that fulfils a medical purpose but that is also intended to drive or influence the use of a medical device is still considered to be MDSW, whereas, according to the IMDRF notes, SaMD cannot drive a medical device. Qualification as MDSW is regardless of:
    - Its location – for example operating in the cloud, on a computer, on a mobile phone or as an additional functionality on a hardware medical device
    - Whether the software, in addition, also drives or influences the use of a (hardware) medical device.

If the software is solely intended to drive or influence the use of a hardware medical device, without by itself creating information for a medical purpose, then it is not considered MDSW but nevertheless is covered by the regulation as an accessory for a medical device or IVD medical device or as an integral part or component of a medical device or IVD medical device

## How are Regulators Addressing the Challenges with Software as a Medical Device?

The IMDRF is a voluntary group of medical device regulators from around the world who have come

together to reach harmonization on medical device regulation. IMDRF develops internationally agreed upon documents related to a wide variety of topics affecting medical devices. In 2013, IMDRF formed the Software as a Medical Device Working Group (WG) to develop guidance supporting innovation and timely access to safe and effective Software as a Medical Device globally. Chaired by the FDA, the Software as a Medical Device WG agreed upon the key definitions for Software as a Medical Device, framework for risk categorization for Software as a Medical Device, the Quality Management System for Software as a Medical Device, and the clinical evaluation of Software as a Medical Device.

## Differences in how the classification process works

Starting at the surface level, here are two key differences between how the US and EU classify SaMD.

- In the EU, the term "SaMD" is not used. Instead, they use the term "medical device software" or "MDSW." MDSW is defined as software that is intended to be used, alone or in combination, for a purpose as specified in the definition of 'medical device' in the MDR or IVDR.
- Under the EU MDR, MDSW is classified through classification Rules 11, 15 and 22, unless it is intended to drive or influence a hardware medical device, in which case other classification rules come into play (outside of the scope of this paper). Note that under the EU MDD, Rules 9 and 10 have also been used to classify independent MDSW, but the MDCG guidance, 9 by not describing these identically worded rules in the EU MDR, hints at regulators not considering them applicable to independent MDSW under the EU MDR.
- In the US, devices fall into three categories: Class I, II, and Class III. In the EU, the MDR distinguishes Class I, IIa, IIb, and III. Further complicating things, the IVDR uses letters instead: Class A, B, C, and D.
- In the US, a manufacturer typically classifies its SaMD by browsing through FDA databases to determine the applicable product code and matching device class. If no code appears to fit, the manufacturer can submit a request for information to the FDA – a straightforward approach that leads to Class I, II or III classification, requiring, respectively, a registration, a 510(k) submission/De Novo submission or a Premarket Assessment (PMA).

Naming differences aside, the key difference in classification is the process of classifying devices. In the US, a manufacturer classifies its SaMD using previous devices as a guide.

To put it simply: In the US, you classify a device by looking through databases to find an applicable product code and matching device class. If there's no code, things become a lot harder. When you're designing a new device and nothing similar has been created before, you have to go through an extensive process with the FDA to get your pre-market approval.

The EU takes a different approach in classifying SaMD. Instead of using prior products as a guide, they use a rules-based framework to classify devices. For in-vitro devices, there are 7 "waterfalling" rules with yes or no questions that lead manufacturers to a classification. MDSW classification is a bit more complex, with 22 rules that must be addressed to get a classification output.

## Differences in length of regulatory approval process

Because manufacturers are able to "self-declare" Class I devices, there's a common belief that you can bring SaMD to market much sooner in Europe than in the United States. However, several low risk devices have been categorized as "under enforcement discretion" by the FDA, meaning that they are recognized as medical devices, but the FDA chooses not to enforce the regulations at this time because the risk to patients is low. Further, the FDA is working to streamline its regulatory oversight of software-based devices, including piloting a software Precertification (Pre-Cert) Program.

The MDR in the EU came into force on May 26, 2021 with the IVDR coming into force May 26, 2022. Under

the MDR and IVDR many software devices have been up-classified, requiring the involvement of a Notified Body, resulting in a 3-6-month review and approval timeline for such devices.

## Bright Insight takes the guesswork out of bringing SaMD to market

Whether you're just starting down the path of developing a new device or looking to future-proof (or region-proof) your digital health roadmap, the Bright Insight Platform was purpose-built to help you bring your regulated products to market. Simply put, we handle global regulatory compliance, so you don't have to.

The health care field is moving faster than it has in the past, and new applications might make us pause and go back to our fundamental goals of assuring safety and effectiveness and discovering alternative paths to reach those goals.

### Conclusion

Placing SaMD on the market has become significantly harder in the EU, whereas the US has removed some of its 'red tape'. In the EU, SaMD classification has become complex, whereas in the US it is very straightforward. The health care field is moving faster than it has in the past, and new applications might make us pause and go back to our fundamental goals of assuring safety and effectiveness and discovering alternative paths to reach those goals. The shift from a purely product focus to a product process viewpoint is a new pathway for the FDA, through which it converges towards the quality management system approach used within the EU. Product developers are innovators. With the explosion of wearables and objects that are part of the Internet of Things (IoT), health and wellness information and technology can be found everywhere. Such apps could run on the computing platform of your mobile phone but also on your fridge or your car. Technology surrounds us to the point that we suggest that humanity has entered an era of 'every wearable's, and this technology will vastly improve our understanding of the human body. Most of these innovations will be driven by software, and most of that software will be SaMD.

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