White Paper

Regulations and Reimbursement of Software as a Medical Device in Europe

Part 2 — Market entry and regulatory landscape

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Introduction

Over the past few decades, the development in software used alone or together with a medical device has increased significantly, this is due, in part, to the increased adoption of smart technology such as smartphones, wireless connectivity, cheaper and better sensors, cloud computing, big data and Artificial Intelligence (AI), which are influencing healthcare delivery across the world.

As advancement of these technologies is shifting how healthcare is administered and delivered, software has become an essential component of the development of medical devices. Particularly "Standalone" software or "Software as a Medical Device" is experiencing rapid growth recently as there is no hardware involved, fewer constraints in addition to the use of fast feedback loops for improvement.

Given the unique features of Software as a Medical Device (SaMD) which extend beyond a traditional medical device or hardware, SaMD brings new opportunities and challenges for both, device companies and for regulators. It is an area in which new regulatory models are being piloted to ensure effectiveness and patient safety without limiting faster innovation growth.

Although reimbursement options for SaMD and digital care in general are not yet standardized, the creation of reimbursement pathways is increasing globally as regulators recognize the role that digital health can play in patient care.

In part 1 of this series we explore SaMD definition, its regulatory challenges and the ways regulators address them, as well as the expected development of regulations related to Artificial Intelligence and Machine Learning in SaMD.

In part 2, we discuss Software as a Medical Device regulations specifically in Europe. We cover Medical Device Software (MDSW) regulations under the EU MDR and the EU IVD, how is it different from the SaMD definition, and we also highlight the key market entry challenges for digital health solutions into the European market.

In addition to this publication, please read part 3 on reimbursement pathways for SaMD, the different segments of reimbursement maturity within the Europeanmarket, and how reimbursement is expected to develop in the coming years.

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European regulatory landscape for SaMD

For digital healthcare providers, bringing a digital healthcare solution into any market is complicated, as each region of the world has its own set of regulatory criteria and requirements.

As a result, a software may be considered a medical device in Europe and not at all in the US or elsewhere in the world. It is therefore important for manufacturers to clearly understand the regulatory pathways for SaMD in Europe and how it may differ from pathways elsewhere.

SaMD regulation in the EU, similar to regulation in the US, does not differ from the way traditional medical devices are regulated. Manufacturers of SaMD need to comply with all the relevant requirements in the EU MDR (the EU Medical Device Regulation) and the EU IVDR (the EU In-Vitro Diagnostic Regulation).

The EU MDR and EU IVDR imply that even 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 (e.g., 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 if it is accessible through, for example, website subscription to a person residing in the EU.[1]

SaMD IN LIGHT OF THE EU MDR REGULATIONS

First, it is important to point out that the EU regulations use the term 'medical device software' or MDSW instead of 'Software as a Medical Device'.

As per the European Commission's Medical Device Coordination Group (MDCG), MDSW is a software intended to be used, alone or in combination, for a purpose specified in the definition of a "medical device", regardless of whether the software is independent or driving or influencing the use of a device.

The software must have a medical purpose on its own to qualify as a MDSW. MDSW may be independent, having its own intended medical purpose and thus meeting the definition of a medical device or in-vitro diagnostic medical device on its own, or it can drive or influence a (hardware) medical device, and also has a medical purpose.

Software may be qualified as MDSW regardless of its location (e.g., operating in the cloud, on a computer, mobile phone, or as an additional functionality on a hardware medical device), and it may be intended to be used by healthcare professionals or laypersons (e.g., patients or other users).

However, when a software is not a MDSW, but is intended by the manufacturer to be an accessory for a medical device or in-vitro diagnostic medical device, then they fall under the scope of the MDR.

Qualifying Parameters for Medical Device Software (MDSW):

- Software which can directly control a (hardware) medical device (e.g., radiotherapy treatment software)
- Software which can provide immediate decision-triggering information (e.g., blood glucose meter software), or can provide support for healthcare professionals (e.g., ECG interpretation software)
- Software which is intended to process, analyse, create or modify medical information may be qualified as a medical device software if the creation or modification of that information is for a medical intended purpose

Instead of SaMD, the EU uses the term 'MDSW' because 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.[1] This brings up a number of important questions: how is MDSW different from SaMD, what are the key similarities and what are the key differentiations between 'SaMD' and 'MDSW', in light of the EU MDR and IVDR regulations?

HOW ARE SaMD AND MDSW ALIKE AND HOW DO THEY DIFFER?

For digital healthcare providers trying to access the European market, the only definition and relevant regulation is the 'MDSW' as regulated by the MDR. However, if the product is to be marketed inside the EU and outside the EU, then it is important to find out whether the software complies with both regulations (both definitions of SaMD and MDSW) (See Table 1).

What do SaMD and MDSW have in common?

Both SaMD and MDSW fulfill one or more medical purposes independently, meaning that the software is not used to control a medical device but has its own medical purpose. For example, a treatment planning system that uses images from various imaging devices to calculate a treatment for a patient.[2]

Both apply to software operating on general-purpose computing platforms, as well as to software running on platforms that are part of a hardware medical device.

- "General-purpose computing platform" means any computer using software to analyze some X-ray images, and that it is not the actual computer where the images are acquired
- "Software running on platforms that are part of the medical device" means an additional software installed on the computer, used to acquire X-ray images

What are the differences between SaMD and MDSW?

Unlike SaMD, MDSW also applies to software that fulfills a medical device purpose on its own but is also necessary for a medical device to achieve its purpose.[3] For example:

- A calculator for Insulin dose that is also necessary to drive the infusion pump (can be an MDSW but not a SaMD)
- The software embedded in a thermometer is considered an MDSW, which is classified as a "medical device" by the IMDRF and MDR, but, in the US, this does not qualify as a SaMD

Table 1: SaMD in light of the EU MDR regulations

MDSW		Non MDSW
SaMD	**Non SaMD**	**Non SaMD**
A Software which fulfills one or more medical purposes independently, i.e., not use to control a medical device but has its own medical purpose, e.g., • Software that helps radiologists and clinicians find and diagnose a cardiovascular condition by analyzing MRI scans • A mobile application that takes input from a blood glucose meter and patient food log to provide insulin dosage recommendations for diabetes	**Software that fulfills a medical device purpose on its own but is at the same time necessary for a medical device to achieve its medical purpose, e.g.:,** • An insulin dose calculator that is also necessary to drive the infusion pump • The software embedded in an electronic thermometer or electronic stethoscope (MDSW intended for diagnosis)	**A software solely intended to drive or influence the use of a hardware medical device, without by itself creating information for a medical purpose, e.g.,** • Software that turns on and controls the X-ray machine • Software used to "drive or control" the motors and the pumping of medication in an infusion pump • Software that encrypts data for transmission from a medical device • Software that monitors X-ray tube performance to anticipate the need for replacement

Source: Internal IQVIA resources.

Additionally, at the international level, SaMD includes software that aggregates information for medical purposes, which is not regulated in the EU. This includes SaMD with limited functionality, such as storage, communication, lossless compression, or simple searching. In other words, all software that handles medical information in hospitals is not considered a medical device in Europe, but it is in some other countries.

This is why we believe it is important for Manufacturers of SaMD, aiming to access the European market, to make sure that their technical file will satisfy the MDR, for their software to also be considered as MDSW.

For this purpose, The European Commission's Medical Device Coordination Group (MDCG) unveiled a Guidance on Qualification and Classification of Software in Regulation (EU)[3], which defines the criteria for the qualification of software falling within the scope of the EU MDR.

QUALIFICATION AS A MDSW ACCORDING TO THE EU MDR

Qualification is the process of determining if software is a medical device according to the MDR or IVDR and should therefore follow the requirements of the EU MDR or the EU IVDR (Figure 1).

In other words, 'Qualification' is a comparison of the intended use of the software and the definition of the Medical Device. If it matches, then the software is called MDSW.

The MDCG provides guidelines to manufacturers regarding whether their software is regulated under the new EU MDR and Invitro Diagnostic Regulation (IVDR). The Guidance offers a step-by-step approach to assist in determining whether software qualifies as MDSW for either a medical device or an in-vitro diagnostic medical device. It also confirms that an MDSW can -be considered a medical device in its own right or as an integral component/part of another device.

Figure 1: Qualifying Software as a Medical Device by European Commission's Medical Device Coordination Group (MDCG)

Active Medical Device

Any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of, or converting that energy.

Software

A set of instructions that processes input data and creates output data.

Medical Device Software (MDSW)

A set of instructions that processes input data (data provided using a human data-input device) and creates output data (data produced by software) and are therefore deemed to be an active device as per the MDR guidelines. The intended purpose of the software described by the manufacturer is relevant to qualifying the software as a device and further addressing its classification.

According to MDCG, SaMD qualifies as such if:
Medical device software is intended to be used, alone or in combination, for a purpose as specified in the definition of a "medical device" in the medical devices regulation (Article 2(1) of Regulation (EU) 2017/745 – MDR) or in vitro diagnostic medical devices regulation (Article 2(2) of Regulation (EU) 2017/746 – IVDR).

According to MDCG, SaMD does not qualify if:
The software is intended as an accessory to a medical device and does not meet the definition of a medical device or an in vitro diagnostic medical device. Then its regulation is covered by the medical devices regulations either as a part/component of a device or as an accessory for a medical device (rules 3.3 and 3.5 described in the Regulation (EU) 2017/745 – MDR or Regulation (EU) 2017/746 – IVDR).

Source: Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR

First, the manufacturer's product must fulfill the definition of a "medical device", "software", or in-vitro diagnostic medical device according to the EU MDR and the EU IVDR. Second, the intended purpose of the software described by the manufacturer must be relevant to qualifying the software as a device and further address its classification under the EU MDR and IVDR.

Decision steps for qualification of a software as MDSW

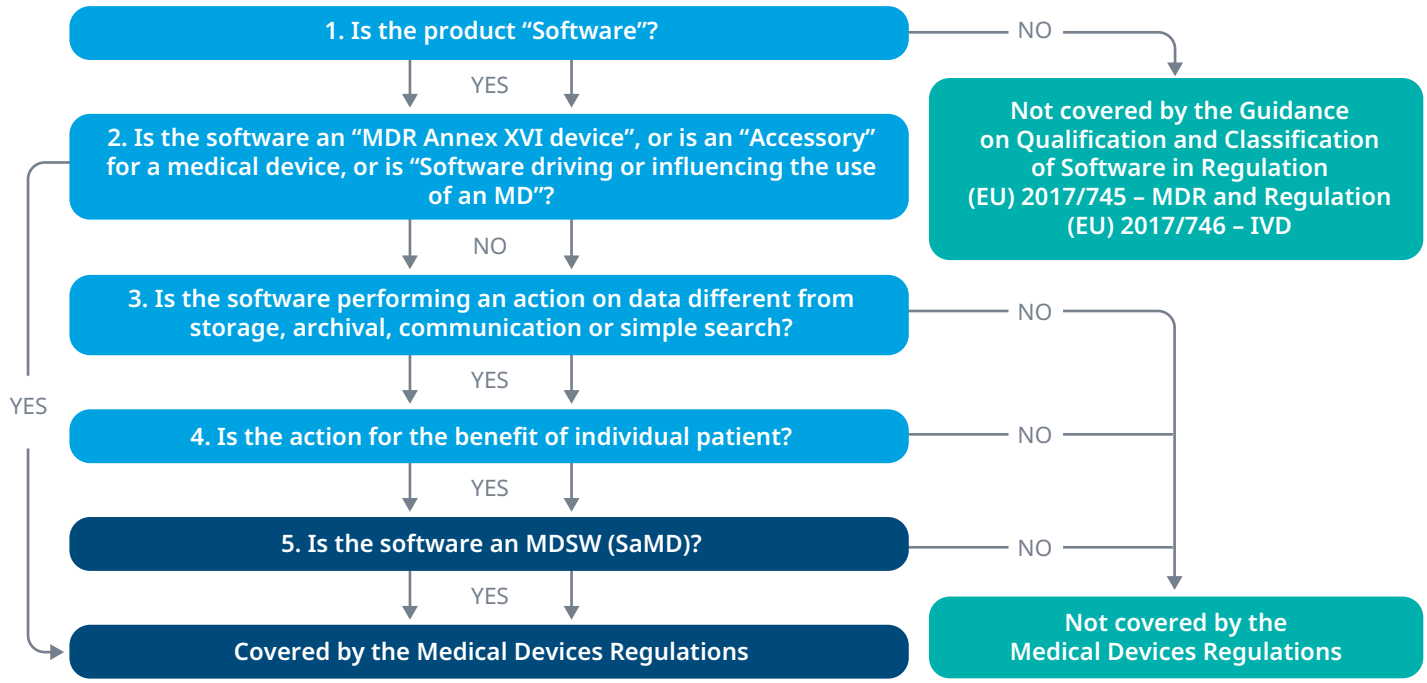
The step-by-step approach to MDSW qualification includes determining whether the software "performs an action on data, or performs an action beyond storage, archival, communication, simple search, lossless expression (i.e., using a compression procedure that allows the exact reconstruction of the original data)". If it does, then it may be considered medical device software.

This step-by-step approach also helps determine whether the software is intended for the benefit of individual patients and not solely for aggregating "population data, provide generic diagnostic or treatment pathways (not directed to individual patients), scientific literature, medical atlases, models and templates).[3]

For digital healthcare providers, bringing a digital healthcare solution into any market is complicated, as each region of the world has its own set of regulatory criteria and requirements.

First, the software must qualify as a MDSW according to the following decision steps (Figure 2):

Figure 2: Decision steps for qualification of software as MDSW and assessment of the coverage by EU Medical Devices Regulations



Source: Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR Note: Medical devices regulations refers to the two applicable regulations EU Medical Device Regulation (MDR; 2017/745), and EU In-vitro Diagnostic Regulation (IVDR; 2017/746)

Second, if the software falls under the definition of MDSW according to the previous decision steps, then the MDSW must be classified either as “Medical device” or “in-vitro medical device” based on the intended purpose (Figure 3).

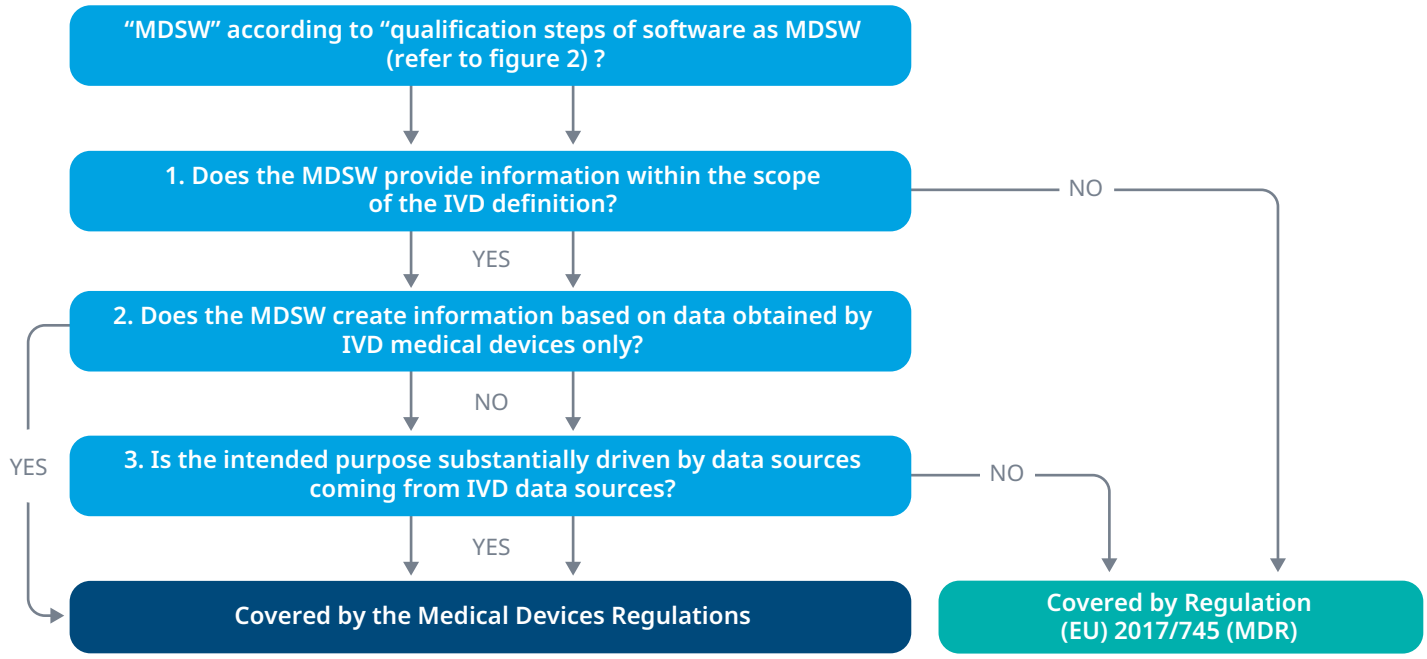
- If the MDSW provides information within the scope of the in-vitro diagnostic medical device definition according to Regulation (EU) 2017/746 – IVDR, e.g., information concerning a physiological or pathological process or state, information to determine the safety and compatibility with potential recipients, or information to predict treatment response or reactions then the software is an in-vitro diagnostic medical device and is therefore an IVD MDSW
- If the MDSW creates information based on data obtained by in-vitro diagnostic medical devices, only then the software is an in-vitro diagnostic medical device and is therefore an IVD MDSW
- If the data analyzed is obtained from a combination of both in-vitro diagnostic medical devices and medical devices, but the intended purpose substantially driven by data sources coming from in-vitro, then the software is an in-vitro diagnostic medical device, and is therefore an IVD MDSW

Otherwise, the MDSW should qualify as Medical Device Software (MD MDSW).

When the intended purpose of the MDSW output data fulfills both the medical device and IVD medical device definitions set out in the MDR and IVDR, a weighting of the data sources based on the significance of the information in relation to fulfilling the intended purpose should be conducted to aid the manufacturer in determining which regulation to apply.

To ensure successful market access, we believe that software manufacturers must first ensure that their software qualifies as MDSW and then make sure it complies with the EU MDR or the EU IVDR regulations to successfully obtain the CE Mark.

Figure 3: Decision steps to assist qualification of a MDSW as either as medical device or an IVD medical device



Source: Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR

Placing a SaMD on the European market: Regulations and key challenges

All medical devices placed on the European market, with the exception of devices that are custom-made or intended for clinical investigation, must bear a CE mark. Once a manufacturer has demonstrated that their SaMD complies with the relevant regulations by the applicable regulatory procedure, they may affix a CE mark to their product and place it on the European market.

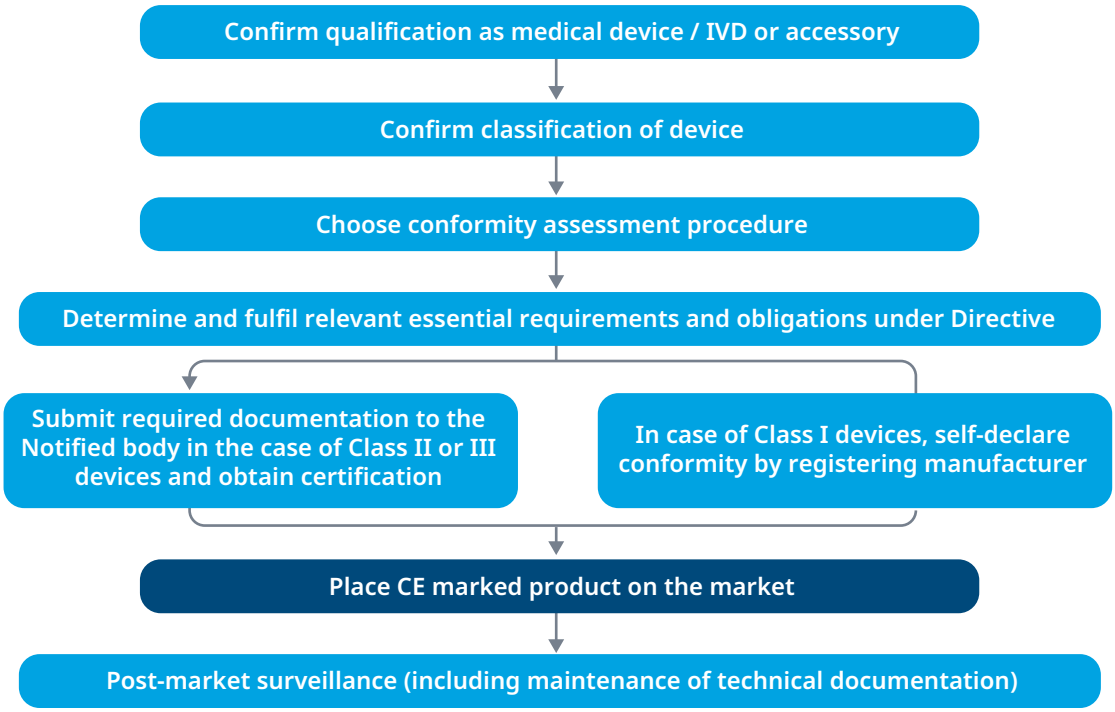
CLASSIFICATION OF SaMD ACCORDING TO THE EU MEDICAL DEVICE REGULATION (MDR)

MDR requirements for market entry mainly depend on the risk classification of the medical device — the higher the risk class, the stricter the regulations are.

The Regulation states that SaMD is considered as an active medical device and as such the classification rules relating to active medical devices apply. Active medical devices are classified into four categories depending on risk to the patient: Class I (low risk), IIa, IIb, III (highest risk). All applicable classification rules have to be applied, and the rule with the highest classification determines the final classification of the SaMD.[3]

In line with the Medical Device Regulation and international guidance from the IMDRF (International Medical Device Regulators Forum), Rule 11 (Table 2)[1,3] was introduced into the MDR which is intended to address the related risks of the information provided by an active device, such as MDSW. Rule 11, in particular, describes and categorizes the significance of the information provided by the active device to the healthcare decision (patient management) in combination with the healthcare situation (patient condition).

Figure 4: Process of placing a SaMD on the European market



Source: Health Products Regulatory Authority (HPRA) Guidance to placing medical device standalone software on the market.

Rule 11 states that[3]:

Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:

- Death or an irreversible deterioration of a person's state of health, in which case it is in class III
- Serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb

Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb. All other software is classified as class I.

For example, according to Rule 11, MDSW that is intended to provide information which is used to take decisions with diagnosis and therapeutic purposes, is at a higher risk class where such decisions are reasonably likely to have an impact that may cause the side effects described in the previous paragraph.

After classification of the MDSW, it is important for the manufacturer to demonstrate the relevant requirements under the EU MDR regulations that apply to their medical device have been met through the conformity assessment and clinical evaluation process.

Table 2: MDCG 2019-11 classification guidance on rule 11

			SIGNIFICANCE OF INFORMATION PROVIDED BY THE MDSW TO A HEALTHCARE SITUATION RELATED TO DIAGNOSIS/THERAPY		
			• Treat • Provide therapy to a human body • Diagnose disease/ condition • Detect disease/ condition • Screen disease/ condition	• Aid in treatment • Provide enhanced support for safe and effective use of medicinal products or medical device • Aid to make a definitive diagnosis • Triage or identify early signs of a disease or condition	• Inform of options for » Treatment » Diagnosis » Prevention • Aggregate relevant clinical information
			High (Treat or diagnose)	**Medium (Drive clinical management)**	**Low (Inform clinical management)**
STATE OF HEALTHCARE SITUATION OR PATIENT CONDITION	**Life-threatening:** • Requires major therapeutic interventions • Time critical • Accurate and/or timely diagnosis vital to: avoid death; serious deterioration of health or to mitigate public health risk	**Critical**	**Class III** MDSW providing information to take decisions for diagnosis or therapeutic purposes that may cause death or an irreversible deterioration of a person's state of health	**Class IIb** (IMDRF example, radiation therapy treatment planning	**Class IIa**
	Moderate in progression /often curable: • Does not require major therapeutic interventions • Not expected to be time critical • Vital to avoiding unnecessary interventions	**Serious**	**Class IIb** MDSW providing information to take decisions for diagnosis or therapeutic purposes that may cause serious deterioration of a person's state of health or surgical intervention	**Class IIb** (MDSW monitoring vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient	**Class IIa**
	• Slow with predictable progression of disease state • Minor chronic illnesses or states • May not be curable • Can be managed effectively	**Non-serious**	**Class IIa** MDSW providing information to take decisions for diagnosis or therapeutic purposes	**Class IIa** MDSW monitoring physiological processes	**Class IIa**

Source: MDCG 2019–11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR (Annex III) Note: This table does not take into account MDSW which is Class I.

CONFORMITY ASSESSMENT AND CLINICAL EVALUATION

A conformity assessment procedure is the process followed by a manufacturer in order to demonstrate that the relevant requirements under the regulations that apply to their medical device have been met.

It is important to note that in the case of a MDSW the type of interconnection between the MDSW and the device (e.g., embedded systems, wires, Bluetooth ,Wi-Fi), does not affect the qualification of the software as a device under the MDR and IVDR (e.g., whether the software is part of the device, or is at a different location).

For MDSW that is classified as Class I, the conformity procedure does not require the intervention of a notified body. For other MDSW Classes, including Class I standalone software with a measuring function, for the CE mark to be affixed, the manufacturer must follow the conformity assessment procedure appropriate to its classification (See table 3).

At this point it is important to point out that while the EU countries have been embracing digital development and use of medical software in healthcare delivery, there remains challenges which medical software providers should keep in mind when expanding into the European market.

There remains challenges which medical software providers should keep in mind when expanding into the European market.

Table 3: CE Mark compliance requirements

DEVICE CLASS	TYPE OF ASSESSMENT	COMPLIANCE REQUIREMENTS	APPLICABLE REGULATION
Class I	**Assessment**	QMS implementation	• Article 10 (9) • Annex IX (Chapter I) and Annex XI Part A (6)
		Technical documentation	• Annex II and III
		Declaration of conformity	• Article 19 and Annex IV
Class Ia	**Notified Body**	QMS implementation	• Annex IX
		Assessment of technical documentation of a Representative Device for each category	• Article 52 Para 6
		Declaration of conformity	• Article 19 and Annex IV
Class IIb		QMS or Type Examination and production QMS	• Annex IX – QMS and Annex X and XI – Type examination and production QMS
		Technical Documentation and QMS	• Annex II and III
		Assessment of Technical Documentation	• Article 52 Para 4
		Declaration of conformity	• Article 19 and Annex IV
Class III		QMS or Type Examination and production QMS	• Annex IX – QMS • Annex X and XI – Type examination and production QMS
		Technical Documentation and QMS	• Annex II and III
		Assessment of Technical Documentation	• Article 52 Para 2
		Declaration of conformity	• Article 19 and Annex IV

Source: MED-TECH Innovation (www.med-technews.com).

KEY CHALLENGES WITH MARKET ACCESS FOR SaMD PROVIDERS

Digital health solution manufacturers, aiming to penetrate the European markets, are met with national and regional fragmentation in data protection rules (GDPR and additional rules), data standards and reimbursement systems.

Complexity of data protection regulatory aspects

From a legal perspective, under the 2018 General Data Protection Regulation (GDPR), the processing of genetic, biometric or health-related data is subject to stricter requirements, including explicit consent from the data subject and appropriate security measures. However, the GDPR allows the processing of such data in certain circumstances, such as for healthcare provision or public health monitoring".[4]

Although the regulation has been adopted for many years now, awareness and full understanding of its legal implications is not widespread. And there is shortage of guidance on how to comply with the transparency, privacy, and security requirements of the GDPR. This is mainly due to the fact that digital health is a rapidly developing business segment.

Fragmented nature regarding data standards across Europe

In addition, Europe's fragmented landscape, both in terms of data standards and rules, limits the capability to collaborate and share health data across Member States. This was seen during COVID, where it was difficult to conduct clinical trials in the EU and had to be done in third countries.[5]

The lack of a streamlined processes for cross-border use of health data in Europe is stalling development of safer and more effective digital health solutions, delivery of more personalized care using real-time data, and advancement of trustworthy artificial intelligence in health.

Technical infrastructure and interoperability

From a technical point of view, the existing gaps in ICT (information and communications technology) infrastructure development across and within countries are an obstacle to the broad and effective market access for digital health solutions.[4]

Additionally, the lack of data interoperability and common standardization hinders the effective communication between different healthcare environments, creating scenarios where health data collected by a hospital are not readable and understandable in another hospital in the same area, let alone in a different region or country.

Digital literacy and trust towards digital solutions

Another set of barriers relates to the still unequal access to ICT services and low digital literacy among a wide segment of the European population. With the rapid pace of digital transformations, the performance of health systems will be closely dependent on how many people have access to digital solutions. Moreover, beyond the question of equal access, acceptance and trust will also play a crucial role.[4]

Funding

The main investments in many European countries are related to EHRs, improvement of health facilities, and the integration processes between hospitals and the communities. However, there are still low levels of investment for eHealth services addressing prevention, diagnosis, and treatment.

The lack of a continuous funding and the challenges involved in the existing reimbursement schemes is a huge obstacle; and even with the existence of funding for innovative technologies, there are no systematic mechanisms to ensure reimbursement.[5]

At the same time, it is important to point out that within these challenges for market entry in Europe, many enablers have been pushing for the increased adoption and use of digital health solutions across Europe mainly due to the growing acceptance of digital health since the pandemic.

In Germany, for example, there have been fewer hospital admissions, and a reduction in all-cause mortality for heart-failure patients, along with improved quality of life due to telemedicine interventions. A variety of telemedicine solutions, such as mobile applications and

websites, are providing virtual medical visits and primary care, e-prescriptions, remote patient monitoring and screening in real time, risk assessment and triage prior to hospital admission.[6]

Other initiatives and policy changes which have been implemented with the aim to facilitate exchange of data in cross-border healthcare are also posting the advancement in medical software solutions in Europe e.g., the Horizon 2020 Work Programme allocated an overall indicative budget of EUR 207.5 million to the call Digital transformation in Health and Care, strengthening digital literacy and promoting the uptake of digital solutions in health are relevant objectives pursued by the EU cohesion policy for the period 2014-2020.[6]

Conclusions

Prior to market entry, it is important for manufacturers to investigate in great detail; determining regulatory aspects and guidelines, drivers and barriers of market access, opportunity for reimbursement, and other funding pathways, as well as data security and data protection requirements for a specific market to ensure a winning market access strategy.

We believe that it is important for medical software providers to explore related regulatory pathways and how they differ from one part of the world to another. Manufacturers aiming to expand into EU must also have a clear understanding of the definitions, classifications, and regulatory process of Medical Device Software.

It is also helpful to have a good understanding of the challenging fragmented nature of the European markets, when it comes to data protection rules (GDPR and additional rules), data standards, and reimbursement systems which can present hurdles for market access of innovative digital technologies in healthcare.

Keep in mind, however, that within these challenges for market entry, there are drivers which have been pushing the adoption of digital health solutions across Europe, mainly due to the growing acceptance of digital health since the pandemic.

Although while achieving funding has been a pain-point for digital health providers trying to expand into the European markets, reimbursement routes for digital healthcare have become more defined in recent years. And even though reimbursement options for SaMD are not yet harmonized on an European level, efforts to develop systematic and dedicated reimbursement routes for digital healthcare, to achieve fast access for innovative therapeutics for patients, have been emerging in many European countries.

This is what we will explore in detail in Part 3 of this series: the current reimbursement pathways for SaMD solutions in Europe (e.g., the DiGA fast track in Germany), the level of reimbursement process maturity within the different European markets, and how reimbursement is expected to develop in the coming years in the UK and France.

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