EU Medical Device Regulation 2017/745:

What does the new MDR mean for medical software and for users?

Overview

Software has become increasingly widespread in healthcare organizations to improve administrative and clinical workflows. While this helps healthcare organizations and professionals to carry out their activities, new challenges are likely to arise regarding the safety of patients. In this context, the new EU medical device regulation (MDR) has been implemented to keep up with modern technology, filling an important legislative gap to regulate the evolution of software as a medical device.

The Regulation entered into force in May 2017 and had a staggered transitional period. On 26 May 2021 come the date of application meaning that from this date compliance to MDR is mandatory to be able to place Medical Devices on the European market.

The EU MDR 2017/45 harmonizes the legislative framework of medical devices with more modern and stricter regulatory requirements than the almost 30-year-old EU directive 93/42/EEC (MDD). The MDR has roughly three times as many articles as the old MDD and, among other topics, it explicitly deals with software as medical device, post-market surveillance, and obligations of the various stakeholders. Although it had been received as bittersweet news for some in the medical device industry, the outlook on patient safety is increased whilst the virtuous companies and healthcare organizations will thrive on the new regulation.

This whitepaper focusses on how the new MDR deals with software as medical device. Following a brief introduction on the regulation, a general overview of the new responsibilities for healthcare organizations is provided. Topics include the requirements pre- and post-sale, what changes for the patients and how healthcare organizations can better implement precautions. The information reported are aimed at giving a more hands-on perspective for users on how to manage software as medical device and better navigate these first years of transition from the MDD.

I. The new Regulation 2017/745

Medical devices are products regulated at EU level, originally by the Medical Devices Directive 93/42/EEC, and today by the new Medical Device Regulation 2017/745. Both govern the design, marketing and post market activities of these types of products.

While the Medical Devices Directive 93/42/EEC required that each country adopted the regulation as national law, creating fragmentation in the conversion in national law, MDR rules are directly applicable to all Member States, which leaves the Member States obliged to adapt their national legal orders to the new framework.

From a legal perspective, the manufacturer shall:

- Define the intended use of the product
- Determine whether or not his product falls within the concept of medical device
- Determine the risk class of the MD (class I–low risk; class IIa, IIb, III–higher risk)
- Perform risk analysis and validation test to demonstrate compliance with the Security and Performance Requirements (Annex I of MDR)
- Draw up a Declaration of Conformity and affix CE marking, for class I
- Shall involve a third party (referred to as the Notified Body–NB) to carry out the activity of verifying; upon positive verification the NB will issue the CE Certification, that allows the manufacturer to issue the Declaration of Conformity and affix CE marking, for class IIa, IIb, III

Software used in healthcare may qualify as a medical device (Software as a Medical Device or MDSW) both when it is included in another medical hardware device (embedded) and when it operates autonomously (stand-alone). To identify the classification, as well as from a legal point of view, it is necessary to define the software's features and intended use. Software is considered a medical device both when it is intended for the purpose of diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap (Article 2 let. A MDR).

In particular, starting with the judgment of the French Court of Justice in the Snitem case (C.329/16), the software qualifies as a medical device if intended to create or modify "medical information, notably by means of calculation process, of quantification or comparison of the recorded data with certain references, in order to provide information about a specific patient."

On the other hand, software does not qualify as a medical device if it will not make "any action on the data or whose action is limited to storage, archive, or compression without data loss, or limited to the simple search to allow you to find information coming from metadata, without modifying or interpreting them."

It follows that, for the purposes of qualification of a medical device, the fact that a software acts or does not act directly on the human body is not relevant. Instead, it is essential that the purpose indicated by the manufacturer is one of those provided for the definition of a device itself.

Lastly, the recent EU document MDCG 2019-11: Guidance on qualification and classification of software in regulation (EU) 2017/745-MDR and regulation (EU) 2017/746-IVDR defines the software as a medical device (MDSW) in the following way "(...) software that 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 or in vitro diagnostic medical devices regulation (...)".

Most important changes related to software in MDR

- Broadens the definition of a medical device and the definition of medical device accessories: it follows that much of the software used in healthcare must now be classified as a medical device
- Introduces new classification rules for which software, classified as a medical device, mainly will fall within class IIa, IIb, III. This means that it's necessary to have a Notified Body for the declaration of conformity (to understand which risk class the software belongs to, please refer to rule 11, All. IX MDR)

II. Which subjects are involved in this change?

The changes to the definition of a medical device in MDR will have consequences for all the stakeholders involved in the medical software supply chain. The introduction of MDR also increases the manufacturing requirements and controls obligations during the distribution phase.

Users will now have a device that is more strictly validated than before in terms of safety and performance levels. Instructions for use of these devices must be respected at all times and now need to be more detailed and specific.

III. Application time of new MDR

MDR shall apply from the 26th of May 2021. However, article 120 provides a transitional period for some medical devices in accordance with Directive 93/42/CEE.

The Medical Device Coordination Group has issued a guideline to define the concept of “significant change”: *MDCG 2020-3 Guidance on significant changes regarding the transitional provision under article 120 of MDR with regard to devices covered by certificates according to MDD or AIMDD March 2020.*

Medical software class I are entitled to remain on the market in accordance with the Directive 93/42/CEE on condition that:

- The declaration of conformity be drawn up before the 26th of May 2021
- The devices continued to be compliant with Dir. 93/42/CEE
- The requirements of MDR, concerning post-market surveillance, supervision, market surveillance, economic operator and medical device registration are respected
- **No significant changes are introduced to the product** (concerning the design and the intended use)

IV. What could be the responsibilities of the user in the event that MDSW breach the requirements of MDR?

As of the 26th of May 2021, the following critical situations may occur:

Software purchase phase	
- Purchase of software non-CE marked - Purchase of software CE-marked ex Dir. 93/42/CEE, whose mark was applied after the 26th of May 2021.	The consequence would be the cancellation of the software contract as well as the possibility of instituting a judgment, by a Court of auditors, for ascribing liability against the public employees involved in the purchase.
Software usage phase	
- The use of a non-CE marked software (purchased before the 26th of May 2021) whose functionalities are covered under the new MDR by the notion of a Medical Device.	The usage is legally permissible, however, being an unmarked product (considered today to be part of the regulated area), the hospital must take responsibility for the use.
- The use of software CE-marked ex Dir. 93/42/CEE with a significant change/modification.	If the healthcare organization understands the significant modification of the software as it relates to the usage, it must request from the manufacturer the statements updated in accordance with MDR. In the case that the significant modification could be undetectable by the user, the health facility can ask the manufacturer to provide updates on the significant changes to the device.

In both cases, if the software causes harm, the contractual liability profiles of the facility toward the patient, must be evaluated.

V. Which precautions can be taken with respect to hardware and software devices by the healthcare organization or healthcare professional?

The software that healthcare organizations should request is software that meets the intended use of the facility and that guarantees the safety of the patient and the user.

According to MDR, in the event that the **healthcare organization itself develops a medical device software,** it is necessary to comply with the articles 5c. 5 MDR, and in particular **it will need to document proof that the specific needs of the patients managed by that product cannot be met from an equivalent device already available on the market.**

This means that, with MDR, a healthcare organization can no longer simply choose between buying an existing medical device on the market or creating a new device internally as was happening with the MDD 93/42/CEE. Now, with MDR, the healthcare organization will need to choose an existing medical device made by an external manufacturer, unless it can prove and document that patient needs can only be met by creating a new medical device in-house.

Procedures to put in action for control and correct use

- **Verify if the software needs CE marking under MDR or not.** To make this assessment it's necessary to know in detail the applicable legislation, the security and performance requirements, intended use and the specific features of the medical device software
- **Respect all instruction for use and indications provided by the manufacturer,** also with regard to compatibility between software and hardware, to the characteristics of computer networking, to the IT security measures, to safeguard against possible unauthorized access etc.
- **Guarantee appropriate staff training** for all users who work with the medical software
- **Define internal procedures to ensure** all users respect the manufacturer's instructions and receive adequate training
- **Evaluate the need to access manufacturer reports in case of significant changes to the device**—in order to verify compliance with the legislation.
- Perform a system wide risk management based, but not limited to, on the provision of IEC 80001-1

VI. What changes for the patient?

The MDR regulation contains, in Annex I, a detailed list of Safety and Performance Requirements that must be respected by all medical devices placed on the market in Europe. These requirements are aimed at ensuring a high security and performance level of the device.

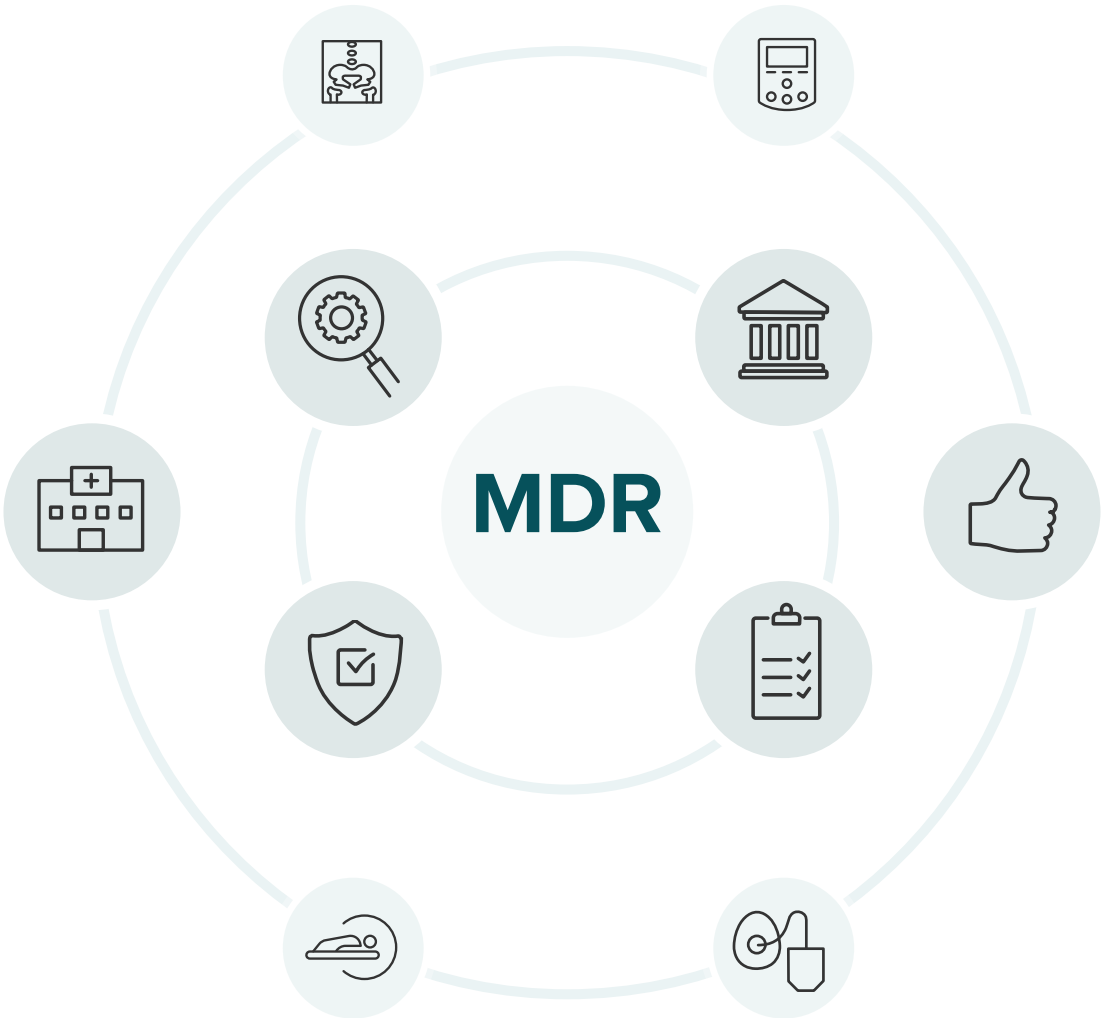
In particular, MDR lists Performance and Security Requirements for MDSW, contrary to Dir. 93/42/CEE, which didn't contain any requirements explicitly for software. Therefore, in contrast to what happened previously and in accordance with the Regulation 2017/745, MDSW today must respect a set of requirements that guarantee high levels of safety, security and performance.

Additionally, MDR increases the obligations of all parties involved in distribution by intensifying control requirements, especially on the performance of the medical device across its entire lifecycle.

Both the new specific requirements and the additional obligations of all parties involved mean that certified MDR software has more advantages for the patient. Indeed, in comparison to software manufactured in accordance with Dir. 93/42/CEE, certified MDR software used in clinical practice will be:

- More robustly tested in terms of efficacy and clinical safety
- Subject to deeper controls and surveillance over its lifecycle

This will create greater safety and performance of the medical device, even when used by inexperienced operators.



Annex

Practical examples: classification according to the Regulation 2017/745 EU

Classification	Practical example	Qualification method
Not medical device	Hospital information system that supports the management of patients' hospitalization process, schedules patient appointments, for insurance and administrative purpose.	The purpose of this device isn't related to the patient's care therefore the software is not to be considered a medical device unless it contains modules that might lead the product to be qualified as a medical device. Examples of these modules are: - *Prescription and medication administration* - *Monitoring of physiological parameters for diagnostic purposes* - *Warnings and clinical alarms (e.g., warning of allergy and contraindications, physiological parameters out of range, warnings on the delay of an intervention/action)*
Class I	Software whose functions can be associated with the storage and saving of data for clinical and epidemiological research purposes.	In this case, the software is used with the aim of predicting a disease, that is set out in the definition's purpose of a medical device. By applying rule 11 of MDR, not forming part of the diagnostic, therapeutic or monitoring purpose, this software is qualified as class I.
Class IIa	Drug treatment planning systems (prescription and administration) used in non-critical environment, for chronically ill patients with slow developing disease.	By applying rule 11 of MDR, these software fall within therapeutic use or monitoring use. For this reason, the software is qualified as class IIa since decisions based on software are unable to lead to death or severe or irreversible deterioration of patient's health (considering external mitigation as in the presence of the doctor).
	ICU patient data management software that includes fluid balance capabilities.	This is a software "intended to monitor physiological process". By applying rule 11 of MDR, therefore these software are qualified as class IIa, since "the nature of the variations of these parameters" is not such as to "create an immediate danger for the patient". Additionally, the decisions based on the software are unable to lead to death or severe or irreversible deterioration of patient's health (in view of external mitigation as in the presence of the doctor).
	Wearable device software intended to monitor patient vital signs at patient's home.	This is a software with the "intended use to monitor physiological process". By applying rule 11 of MDR, these software are qualified as class IIa as "the nature of variations of these parameters" is not such as to "create an immediate danger for the patient". Additionally, the decisions based on software are unable to lead to death or severe or irreversible deterioration of patient's health (in view of external mitigation as in the presence of the doctor). In fact, in their intended use, these devices cannot include monitoring patients with rapid-course diseases (e.g. severe cardiac arrhythmias) as, being monitored at home, there would be no chance to intervene and rescue.

Class IIb	ICU patient data management software that includes the management of infusion therapy with automatic calculation of dosages based on parameters entered (patient weight, drug concentration etc.)	This is a software “intended use to monitor physiological process”. By applying rule 11 of MDR, these software are classified as software with therapeutic or monitoring purpose. The software falls into class IIb as the decisions based on the software’s use are able to lead to death or severe or irreversible deterioration of patient’s health: an incorrect dose, given the limited time available for decisions in intensive care, wouldn’t give medical staff the chance to rectify the situation and it could lead to severe deterioration of the patient’s health.
	ICU patient data management software that displays real time data acquired from medical device, including physiological parameters and replicating the alarms.	This is a software with the “intended use to monitor physiological process”. By applying rule 11 of MDR, these software are classified as class IIb as “the nature of the variations of said parameters” is “such as to create an immediate danger for the patient”. In addition, the decisions based on the software’s use are able to lead to death or severe or irreversible deterioration of patient’s health: an incorrect decision, given the limited time available for decisions in intensive care, wouldn’t give medical staff the chance to rectify the situation and it could lead to severe deterioration of the patient’s health.
	Software for the calculation and display of diagnostic and therapeutic scores used to influence doctors’ therapeutic or diagnostic’s judgment in critical area context.	This is a software with the intended purpose of "therapeutic or diagnostic use". Therefore, applying rule 11 of the MDR, these software fall under therapeutic or monitoring use. The software qualifies as class IIb since it is used to take decisions that are capable of leading to death or a severe or irreversible deterioration of patient’s health (in a critical context): an incorrect decision, based on the score, could lead to incorrect treatments and, given the severity of patients in intensive care, it wouldn’t give the healthcare staff a chance to remedy the situation and could lead to a serious deterioration of the patient's health.

Practical examples

Significant changes: All examples below are software changes that lead the existing MDD CE marking of the software to be invalid and therefore require the software to be CE marked under MDR.

Change		Example
Changes to the intended purpose.		Prescription and administration functionalities are added to the purpose. Registration and management of allergies are added to the purpose. Diagnosis, monitoring, prediction, prognosis, treatment or mitigation of diseases (all fall under medical purposes of article 2 of MDR) are added to the purpose. The type of patients that can be managed in the software is extended with respect to the original purpose (e.g. pediatric patients).
Design or performance changes.		User interface needs to be revalidated with new usability data if adding touch screen and a new pointing tool (e.g. mouse). New risks have emerged or the risks in the application use have worsened: for example, it's recognized that medical staff often make mistakes introducing values (e.g. drug dose) and therefore its risk analysis must be increased. New alarms have been added: for example, patient allergy alarms, new values of physiological parameters' alarms etc.
Software changes	Drug treatment planning systems (prescription and administration) used in non-critical environment, for chronically ill patients with slow developing disease.	An executable file is added to the software to provide a new additional functionality. A table containing physiological parameters used for diagnostic purpose is added to the software. The database engine is changed (e.g. from Oracle to SQL). A new algorithm for medical use is introduced to the software, for example: - *Substitution of the algorithm used to calculate fluid balance* - *BSA calculation algorithm is introduced* - *Algorithm for checking drugs incompatibility is introduced* - *Algorithm for verifying that the age for a drug corresponds to the patient's age*
	Therapeutic or diagnostic features are introduced or changed.	The possibility to manage new routes of medication administration (e.g. infusion) with use of dedicated software controls has been added. A warning that indicates a medication may not be effective given the patient's physiological parameters has been added.
	New user interface or way to present data.	The user interface is changed to support new functionalities: - *Sound is added to alarms* - *A new system for physiological parameters' visualization is implemented* - *As a consequence of the introduction of new physiological parameters, the user interface is changed to support accordingly*

Non-significant changes

Any changes, in order to be considered not significant, must not have an impact on the performance and intended purpose of the medical device.

Change	Example
Fixing a bug that is not going to change the approach to risk management for patient safety.	Software stops working when a value 0 is entered as a consequence of a division by zero.
Security updates such as installation of a security patch.	Encrypting data algorithms are being improved; introduction of 2-stage authentication.
Simple issue of user interface.	Addition of the company logo.
Change in operational efficiency.	Increase the speed of the software by removing useless code.
Changes to improve user interface without modifying the medical device's performance.	When clicking a button, it produces a clicking sound to give audio feedback.

MDR and the Ascom Healthcare Platform

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For any questions about how MDR is handled by the Ascom Healthcare Platform—or if you are investigating communication and collaboration software in your own environment—do not hesitate to contact your local Ascom representative for more information or guidance.

ascom

Ascom Holding AG
Zugerstrasse 32
CH-6340 Baar
Switzerland
info@ascom.com
Phone: + 41 41 544 78 00
ascom.com

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