Software as a medical device - An MDR Guide

White Paper - June 2020 - Edition 1

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About the author and Mantra Systems Ltd

Mantra Systems Ltd delivers a completely new form of medical device regulatory support. Unlike any other consulting company, we have a team of specially-trained medical doctors who apply their clinical acumen and industry expertise to your medical device compliance challenges. With the new MDR focusing heavily on clinical evidence, our knowledge will provide the support you need to ensure your devices meet the requirements of the MDR.

This White Paper is part of a series written by Dr Paul Hercock, the CEO & founder of Mantra Systems Ltd. Paul is dual-trained in medicine and law. He spent 14 years working for the NHS as a front-line clinician and then obtained a Graduate Diploma in Law with distinction from Nottingham Law School. While at law school, Paul established a medical device start-up. He then went on to specialise in providing medical and regulatory support to multi-national medical device companies from across the industry.

Leveraging Paul's expertise, Mantra Systems comprises an infrastructure of specially-trained medical doctors that apply their clinical knowledge to provide support services to medical device manufacturers working to achieve compliance of their medical devices with the MDR.

Introduction - Software as a medical device

The Medical Device Regulation MDR 2017/745 represents the largest overhaul of medical device legislation in decades. Fully in force from 26th May 2021, the MDR introduces a wide range of changes including an extended definition of what constitutes a medical device. Following significant advances in the complexity and availability of software over the past decade, many types of medical software will fall within this extended definition and be subject to the full scope of the MDR.

In this White Paper, we outline how to establish whether or not the MDR applies to a software product. In many cases, determining whether or not software will be classed as a medical device is far from straightforward, especially given the huge array of functions and purposes across the spectrum of available medical software. Understanding whether or not the MDR will apply to a product is a key first step in developing a product compliance strategy beyond May 2021.

Mantra Systems offers a complete range of tailored MDR services through which our team of medical experts will design, implement and maintain full MDR compliance support packages for software as a medical device. We also offer an online training workshop that is designed to enable you to understand your range of responsibilities under the MDR.

Contact a member of our team today to discuss your requirements.

What is medical device software?

Medical device software is software that is intended by the manufacturer to be used for a medical purpose and meets the Article 2 MDR definition of "medical device". From the perspective of software products, this definition can be interpreted as:

> ***...any software, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:***
>
> *diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,*
>
> *diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,*
>
> *investigation, replacement or modification of the anatomy or of a physiological or pathological process or state.*

Superficially, it may appear surprising that software could be classified as a medical device. A medical device is perhaps more traditionally viewed as a hardware product intended to treat, alleviate, predict, diagnose or prevent disease. However, software is increasingly capable of fulfilling the same objectives as hardware, meaning that regulating software in line with physical devices makes intrinsic sense.

The increasing sophistication and complexity of medical device software meant that the scope of existing regulatory provisions in the Medical Device Directive (MDD), soon to be formally replaced by the MDR, had been exceeded. AI applications that can interpret radiological images, software that can make diagnoses or predict disease from input parameters, and an expanding range of smartphone apps are just some examples that go beyond medical device software as originally conceived. The MDR introduces a range of regulatory changes that aim to close this gap and it is vital that software producers understand their responsibilities under the MDR.

This White Paper is intended to help software manufacturers understanding the position of their products with relation to the MDR. It outlines a framework for determining whether a software product will be regulated under the MDR according to its intended purpose and functionality.

More information on risk classification and building an MDR compliance strategy can be obtained from a member of our team.

Is my software a medical device?

Not all software associated with the provision of healthcare will be classified as a medical device. Medical device legislation is intended to apply only to software whose intended purpose is in line with the Article 2 definition outlined above. However, because medical software performs such a vast array of purposes across healthcare, it is not always easy to determine whether or not the Article 2 definition applies.

Software must have a **medical purpose on its own** in order to be classified as a medical device. This is important to consider with respect to 'stand-alone' software such as a diagnostic app, but even more important when software is an integral part of, or associated with, a hardware device.

Determining whether or not software has a medical purpose depends partly upon the **intended purpose specified by the manufacturer**. Although a medical purpose can be inferred even if not intended by the producer, this will only apply to a minority of cases. The location and form of software is irrelevant when considering whether it is a medical device, as is, surprisingly, the likely risk to patients (although the latter is considered when applying risk classification to software that does meet the definition of medical device).

For the purposes of understanding whether or not an individual software product may be subject to the MDR's rules, it may be helpful to consider several categories of function and purpose:

1. Basic support/admin software
2. Simple archive and retrieval
3. Archive, retrieval and modify
4. Data interpretation, advice and/or call-to-action
5. Independent 'smart' diagnosis/prognosis/analysis
6. Mixed purpose/modular software
7. Combined hardware/software
8. Closed loop products
9. Contraceptive support

1) Basic support/admin software

Software that performs a basic admin function such as organising staff rotas, coordinating clinic visits or facilitating staff payroll will not meet the definition of a medical device. Although software in this category performs a function that is allied to healthcare, the

software does not have an intended medical purpose and the provision of care itself is not directly impacted by the product. Another way to view this is that such software could easily be substituted by a paper-based system without any impact on the provision of care.

Example i): A system that co-ordinates weekend duty for a team of junior doctors. Although coordinating the work pattern of medical staff, this software would not **on its own** have a medical purpose and would not be classified as a medical device.

2) Archive and retrieval software

Software intended to serve as a simple database of information, allowing data to be stored and retrieved without being manipulated, would not be classified as a medical device. For example, an electronic patient record viewer system is unlikely to meet the definition of Article 2 if it simply allows workers to access medical records without altering or enhancing their content in any way. Similarly, an app that enables a patient to store serial blood pressure readings without interpreting or adding 'medical value' to the stored data would also be unlikely to qualify as a medical device.

Complexities can arise if the software in question does more than just archive and retrieval. If the software modifies the information in some way, the type of modification has a bearing on how the software will be classified. If the product assists medical decision making - for example by highlighting a worrying blood pressure or advising a doctor's appointment based on the pattern of blood pressure readings over time, this would be classed as a medical purpose and would draw the app under the MDR's jurisdiction. On the other hand, a simple alteration of the way data is represented (for example, by graphs) or a cosmetic embellishment of the data is not likely to count as a medical purpose.

Example ii): an app that simply logs blood glucose levels and does nothing else. In this case, the app would have a simple storage and retrieval function and would not be classed as a medical device. This would be the case even if the app altered the way the data was represented, so long as that alteration did not serve to assist medical decision-making or influence care.

3) Archive, retrieval and modify

This category goes beyond the functionality offered by simple archive and retrieval software and adds 'medical value' to the information stored within it. This added functionality may be intended to assist medical decision-making, or create alerts of impending health

deterioration. This type of functionality is likely to be held to have a 'medical purpose' and this category of software will fall under the MDR.

Example iii): an app that logs blood glucose levels and highlights aberrant readings. By contrast to the similar app described in Example ii) above, it should be clear that this app goes beyond simple storage and retrieval and is adding 'medical value' to the basic data. The functionality of the app has the potential to alter treatment and it would appear reasonable that it should be classed as a medical device.

4) Data interpretation, advice and/or call-to-action

This category of software adds yet another layer of complexity and medical functionality. By offering advice and/or a call-to-action, it should be clear that the likelihood of this type of software will impact medical care is even higher than previous categories. Software of this type applies a level of reasoning and interpretation that goes well beyond simple data storage and retrieval.

Example iv): an app that logs blood glucose levels and advises on insulin dose based upon an interpretation of those readings. The addition of specific advice that impacts medical care clearly draws this type of app under the MDR.

5) Independent 'smart' diagnosis/prognosis/analysis

Software of this type is becoming more prominent and more important in the provision of modern healthcare. Intelligent software that can assist or replace human-driven diagnosis or prognosis has the potential to reduce workload burden and eliminate the potential for human error. Software in this category clearly has a medical purpose and would be subject to the MDR almost without exception.

Example v): software that analyses photographs of skin rashes and provides a diagnosis from appearance. The software in this example is using 'intelligence' to provide a diagnosis. This is a clear medical purpose and the product would be classed as medical device software.

6) Mixed purpose/modular software

In some cases, several of the above (and other) categories may be combined into one product, with some components (or modules) having a medical purpose and others not. This can lead to a confusing picture from a regulatory perspective and it is important that producers understand how to proceed.

The MDCG 2019-11 advisory document published by the European Commission explains that only the modules with a medical function would be subject to the MDR. It is the responsibility of the manufacturer to determine where the division between modules falls.

Example vi): Software that stores and ensures retrieval of medical records and analyses the records for data trends that suggest increased risk for myocardial infarction. In this example, the module that performs a simple storage and retrieval function would not be subject to the MDR, but the module that is analysing the data trends would be. Regulatory work would only have to be undertaken for the analysis module, with no MDR work required for the retrieval component.

7) Combined hardware/software

A vast array of physical medical devices now have software as an integral or associated component. In some cases the software concerns itself only with driving the function of the hardware (such as firmware that drives the actions of a PCB). In other cases the software will have a medical purpose in its own right. The physical medical device will naturally be subject to the MDR, but how about the software?

Example vii): An electronic blood pressure machine has on-board software that causes the cuff to inflate in response to the user pressing a button. In this case the software does not have an independent medical purpose and forms an integral part of the hardware device. This is an example of software that is **driving or influencing the use of a medical device** and all such software will be similarly regulated. The software **would** in fact fall under the MDR (since it is necessary for the function of the hardware device) but would not necessarily have to undergo its own regulatory assessment. Rather, the medical device software will be assessed through the regulatory process applied to the device as a whole. The risk classification of the combined hardware/software product would be the highest class that could apply to either component in isolation, according to the rules in Annex VIII MDR.

Example viii) An electronic blood pressure machine has on-board software that inflates

the cuff, analyses the reading, and advises on the dose of intravenous blood pressure-reducing medication. In this case the software has an independent medical purpose in its own right, regardless of the fact that it is packaged as a component of the hardware device. It would need to undergo its own regulatory assessment and may occupy a higher risk class than the hardware device to which it relates.

8) Closed loop products

Closed loop products are a special case of combined hardware/software devices. A closed loop product performs an integrated action wherein a parameter is measured, an analysis is performed, and an action is taken as a result of that analysis. Under the MDR, such a combination would be a medical device and would be subject to provisions required for Class III devices.

Example viii): An automated external electronic defibrillator. This type of device would record ECG waveform, perform an internal analysis, and administer a defibrillation shock if the analysis suggested this was appropriate. This would meet the definition of medical device according to Article 2 MDR because it performs an integrated diagnostic function which significantly determines the patient management by the device. Such devices are subject to a dedicated classification Rule in Annex VIII MDR, which classifies them as Class III.

9) Contraceptive Support

Software products such as apps that provide contraceptive information or support are increasingly popular, offering the potential for an effective form of contraception without the need for hormonal modulation. Although conception is a non-pathological process (and would not therefore be caught by the definition of 'medical device' in Article 2 MDR), software of this nature would in fact be classed as a medical device. Rule 15 of Annex VIII states that "All devices used for contraception... are classified as class IIb, unless they are implantable or long term invasive devices..."

Example ix): An app that analyses fluctuations in body temperature to identify when a woman is fertile, in order to function as a contraceptive. This app would be a medical device and would need a full regulatory assessment in its own right.

Conclusion

As can be seen, determining whether an item of software will be subject to the MDR can be complicated. We hope that the summary and structure provided in this White Paper has been helpful in understanding whether or not your products will need to be regulated under the MDR.

At Mantra Systems, our mission is to bring medical expertise to producing MDR compliance strategies for our clients. We work with all types of medical devices including and especially medical device software. Our expertly-trained medical professionals will apply their clinical acumen to develop the evidence portfolio and compliance structure you need to ensure ongoing availability of your products after May 2021. **Contact us today to discuss your requirements at:**

- **Tel:** +44114 386 3349
- **Email:** contact@mantrasystems.co.uk

We also offer a range of exclusive training programmes including a dedicated seminar **"Software as a medical device - an MDR guide"** that will enable software developers to understand their full range of responsibilities under the MDR, including:

- understanding risk classification
- clinical evaluation
- generating evidence for software devices
- post-market surveillance
- PMCF strategy.

Visit www.mantrasystems.co.uk/mdr-training/events for more details.