



AAL and the new EC Medical Devices regulation

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Executive summary

The objective of this paper is to give the AAL community a framework to help understand the new EU Medical Device legislation and its requirements. It also provides perspective on how the EU Medical Device Regulation affects the development of solutions targeting active and healthy ageing. We present our perspective on how to qualify and classify a product as a medical device and explain the classification's impact on the certification route. The manufacturer is required to identify the product's applicable General Safety and Performance Requirements (GSPRs). Conformity with these GSPRs will be achieved by applying standards during the design and development phase and evidence is collected as part of product verification and validation. Additionally, a product risk analysis must be performed and clinical data substantiating the product's safety and performance must be gathered. The collected evidence is compiled into the technical documentation and is supplemented with a plan on how to monitor the device performance and risks in the post-market phase. This technical documentation will be assessed by a notified body (except for Class I devices). Besides, manufacturers need to implement a quality management system to ensure reliable and consistent product quality, safety, and performance. After obtaining regulatory approval, manufacturers are required to report incidents with their device. They also need to inform their notified body about changes to their product(s) or organisation for which the notified body has delivered a CE-certificate and a quality management system certificate, respectively.

The EU MDR entails an important impact in terms of time and resources required to obtain regulatory approval of a medical device that also producers of solutions targeting an active and healthy aging through ICT should bear in mind. Given these constraints, as a manufacturer it is essential to be aware of the regulatory requirements as from the concept phase to apply them during the design and development of the solution. Failing to take the regulatory strategy into consideration when preparing the commercialization strategy, might lead to substantial delays in placing the product on the market.

Statement of originality

This document contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation, or both.

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Introduction and scope

What is the aim of this AAL paper?

The aim of this document is to provide the Active and Assisted Living (AAL) Community with an understanding of the EU Medical Device Regulation 2017/745¹ and more specifically to help understand whether their solutions for Active and Healthy Ageing (AHA) would qualify as a medical device. Additionally, it intends to explain the certification process necessary to obtain CE marking as a medical device in Europe. The paper is targeting software only solutions, hardware solutions and solutions integrating hardware and software. This paper will not touch upon the requirements of the *in vitro* diagnostic medical devices regulation 2017/746².

To whom is this paper addressed?

This document is designed for all researchers, developers, policy makers, start-ups and innovators in the AAL domain. It can support the successful commercialisation of their solutions by integrating the regulatory perspective as from the development stage of products and services.

Why is this paper important?

Qualifying a solution, targeting active and healthy ageing, as a medical device has a huge impact on the time to market and the required resources. Understanding the regulatory requirements and their implications early in the product lifecycle is fundamental to successful product commercialization.

¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02017R0745-20200424>

² <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02017R0746-20170505>

To be or not to be a medical device

Qualification as a medical device

Solutions that are developed in the Active and Healthy Ageing (AHA) field encompass many different applications. They vary from wearable devices that improve both mental and physical wellbeing for elderly, to solutions for personalised meal recommendations to maintain a healthier lifestyle (lifestyle and well-being purposes). Other solutions tackle disease management and medical care of chronic obstructive pulmonary disease (COPD) patients by modifying the patients' treatment program, or even suggesting hospitalisation. Some other solutions are targeted towards self-management of dementia which combine risk assessment and early detection of deterioration symptoms of the patients with social networking and educational tools.

Some of the (no exhaustive) solutions described above will qualify as a medical device, others will not. The EU Medical Device Regulation 2017/745 is applicable to products complying to the definition of a medical device³ and to accessories⁴ for medical devices. Medical devices cover a broad variety of products, from (mobile) software solutions to hardware systems, from implants to instruments, but also orthoses or contact lens liquids are medical devices. Solutions intended to improve the wellbeing of a user do not correspond to the definition of a medical device, since they do not treat/alleviate a disease. The lifestyle and well-being solutions described in the first paragraph of this section fall within this category. Patient disease management tools on the other hand, might have a medical purpose since they intend to treat/alleviate a specific disease (cfr. COPD disease management tool described in the first paragraph of this section). However, software solutions operating in the healthcare sphere do not always qualify as a medical device. Software must be intended by its manufacturer for one or more of the medical purposes listed in the definition of a medical device, such as diagnosis, prevention, monitoring, treatment, or alleviation of a disease.

An example of medical device software is software generating new information by analysing data received from external sources (for example, a blood pressure meter, a wearable, an electronic health record...), whereby this new information is used to inform a healthcare practitioner or lay user about the progression of a disease. Software performing storage,

³ 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article 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,
 - providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,
- and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

⁴ 'accessory for a medical device' means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s)

communication or simple search of medical data is not considered a medical device, for example software only gathering and visualising data measured by a medical wearable.



Decision steps to assist qualification of **Medical Device Software (MDSW)**

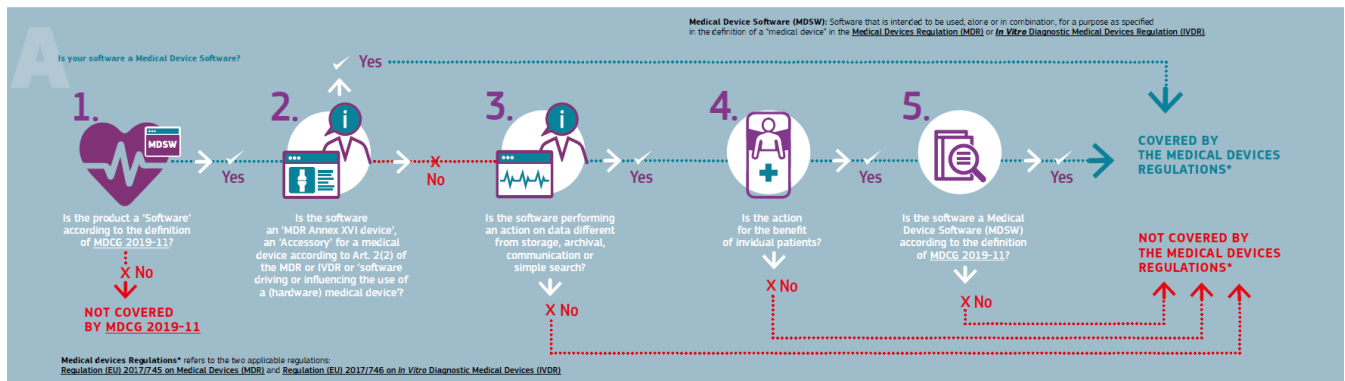


Figure 1: Is your software a medical device? Decision steps to assist qualification of Medical Device Software⁵

Given the fact that qualifying software as a medical device is a difficult task, with heavy consequences in terms of time, money, and responsibility, developers/manufacturers can consult existing guidance⁶ and Figure 1, for more information. Technological advances in information and communication technologies such as artificial intelligence and virtual reality but also wearables led to a bigger share of software-driven applications in medical practice. To keep up with this state-of-the-art, the European legislation on medical devices was updated with new rules, including one rule specifically dedicated to software (rule 11).

Medical device classification

As soon as a product qualifies as a medical device, it must be classified according to the legislation’s classification rules⁷. Medical devices are classified according to the risk they carry for the patient or intended user: class I (low risk), class IIa or IIb (medium risk) or class III (high risk).

The medical device classification influences the product’s path towards regulatory approval: the requirements become stricter as the risk class of the device increases. The involvement of a Notified Body is not necessary for class I medical devices, unless they have a measuring function, are placed on the market in a sterile condition or are reusable surgical instruments. In the former case, manufacturers can place the CE marking on the product themselves after implementing a quality management system (QMS), establishing the technical documentation

⁵ https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2021_mdsw_en.pdf

⁶ MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR

⁷ EU MDR 2017/745 Annex VIII

and drawing up the Declaration of Conformity (DoC) to declare the conformity of the product to the medical device legislation. For the latter and for class IIa, IIb and III devices, the technical documentation is submitted to a notified body who assesses the conformity of the product with the requirements of the legislation. Additionally, the manufacturer’s quality management system is audited and certified. See EU MDR 2017/745 articles 10⁸ and 52⁹ for more information.

To develop a successful commercialization strategy, it is fundamental to understand early in the product lifecycle the impact of the risk classification on the project timeline and resources.

Regulatory requirements when placing a Medical device on the market

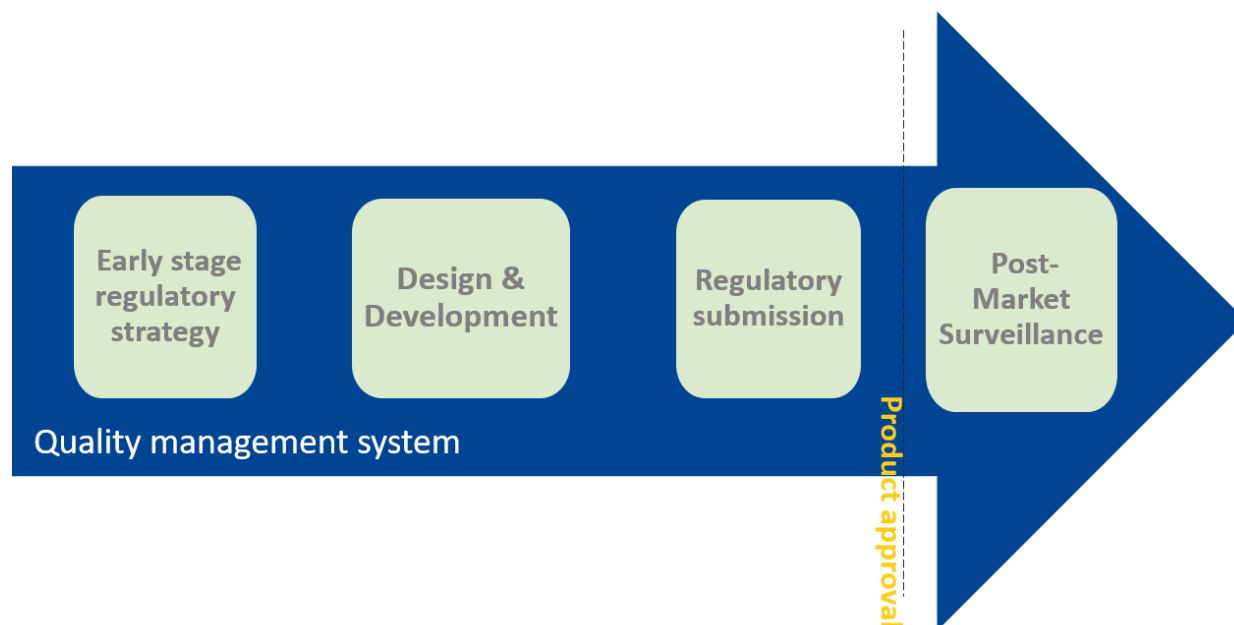


Figure 2: Regulatory roadmap for a medical device

Early-stage regulatory strategy

During the concept phase, based on the solution’s intended use, the manufacturer confirms whether it qualifies as a medical device and thus needs to comply to the EU MDR. Although the EU MDR is the most stringent and demanding legislation regarding medical devices, developers should be aware of other relevant EU laws that could apply. Software intended to process personal data might additionally need to comply to the General Data Protection Regulation (GDPR), whereas medical device hardware might need to comply to the directive

⁸ Obligations of manufacturers

⁹ Conformity assessment procedures

on Waste from Electrical and Electronic Equipment (WEEE). The new EU MDR replaces two old EU directives, Medical Device Directive (MDD) and Active implantable Medical Device Directive (AIMDD). The new regulation is more extensive and stricter than the old directives. The changes impact all stakeholders including manufacturers, importers and distributors, but also health institutions, competent authorities and notified bodies.

During this phase, the most appropriate conformity assessment route to be followed is chosen. Mostly, manufacturers chose to implement and certify a complete quality management system for the design, development, production and distribution of the medical device. At the same time, the product's applicable general safety and performance requirements (GSPRs) (Annex I of EU MDR 2017/745) are identified. During the design and development phase, evidence of conformity with these GSPRs will be generated and collected in the technical documentation. This technical documentation will be assessed by a notified body (except for Class I devices, cfr. above).

Medical device design, development and testing

The General Safety and Performance Requirements (GSPRs) are high-level requirements. They can be met by applying (product specific) standards, such as standards for medical electrical equipment (EN 60601-1¹⁰), usability engineering (EN 62366-1¹¹) or software life-cycle processes (EN 62304¹²), that represent the state-of-the art. Evidence of compliance to these standards (and thus to the GSPRs) will be generated during design verification and validation. Design verification tests whether the solution meets the (performance) requirements, whereas design validation evaluates whether the final device (or an equivalent) meets the user needs during actual or simulated use. Medical device performance, for example the accuracy of an algorithm, can be evaluated with anonymised retrospective patient data. Product usability can be evaluated by observing healthcare practitioners and/or patients whilst operating the device. Depending on their setup, these tests might require approval of an Ethics Committee.

EU MDR emphasizes strongly risk management¹³ and this is also reflected in the GSPRs. One GSPR states that risks associated with the use of a medical device must be acceptable when weighed against the benefits for the patient. Risk is understood as the combination of the probability of occurrence of harm (the harm is not expected to occur during the lifetime of the medical device, likely to occur a few times, likely to occur frequently, etc) and the severity of that harm (death or loss of function or structure, reversible or minor injury, no injury or slight injury, etc), towards the patient, the care provider, and the treatment environment. The manufacturer must perform a product risk analysis and prove that the product's overall residual risks are acceptable, in relation to the state-of-the art, when used as prescribed by the manufacturer.

The demonstration of a product's safety and performance requirements, the evaluation of the product's undesirable side-effects and the acceptability of the benefit-risk ratio must be based

¹⁰ Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

¹¹ Medical devices - Application of usability engineering to medical devices

¹² Medical device software - Software life-cycle processes

¹³ Please refer to EN ISO 14971 for more information

on clinical data, applicable to the device. Clinical data can be generated through clinical investigations of the concerned solution, can be retrieved from scientific literature or can be retrieved from post-market surveillance activities such as post-market clinical follow-up (see infra). Clinical investigations with medical devices that are not yet CE marked and that involve one or more human subjects, fall under scrutiny of the relevant Competent Authority and need to be approved¹⁴ before initiation.

Technical documentation preparation, quality management system implementation and regulatory submission

The data and evidence generated as part of product verification/validation, results from the clinical evaluation, supplemented with the device description, labels, instructions for use, production and other information are compiled into the technical documentation as described in Annex II of EU MDR 2017/745. In addition to these pre-market data, the manufacturer must prepare a Post-Market Surveillance (PMS) plan to collect and evaluate data on the device from routine use. This entails both reactive processes to monitor complaints and update product risks, but also requires analysis of proactive data sources, for example publicly available information about similar medical devices. As part of PMS, to fill gaps in pre-market clinical data, the manufacturer might need to conduct Post-Market Clinical Follow Up (PMCF). PMCF confirms the safety and performance throughout the expected lifetime of the device, ensures the continued acceptability of identified risks and detects emerging risks based on factual evidence.

When the technical documentation is finalised, the manufacturer writes the Declaration of Conformity thereby confirming that the product complies to the EU MDR. After the manufacturer's Quality Management System is certified or in parallel, the notified body can assess the technical documentation, and finalize the conformity assessment.

A successful conformity assessment leads to the issuing of a CE certificate and a Quality Management System certificate. The manufacturer completes the Declaration of Conformity with the CE certificate number and applies the CE marking symbol accompanied by the notified body number to the product.

Additionally, the manufacturer needs to register its information and the medical device(s) (accompanied by a unique device identifier) in the European database on medical devices EUDAMED¹⁵. This database is intended for market surveillance purposes by competent authorities and it allows the public to retrieve information on medical devices marketed in the EU.

Post-market surveillance

The notified body's role does not cease after the device is placed on the market. To maintain a high level of safety for patients throughout the expected lifetime of the device, the notified body will perform yearly surveillance audits of the manufacturer's quality management system. The notified body assesses how manufacturers perform post-market surveillance, and how

¹⁴ Except for clinical investigations with investigational class I devices or non-invasive class IIa and class IIb devices, unless otherwise stated by national law, that can start immediately after the validation date of the application (EU MDR 2017/745 article 70).

¹⁵ https://ec.europa.eu/health/md_eudamed/overview_en

their findings feed into the clinical evaluation report. During these yearly audits it is assessed whether the manufacturer's QMS certificate can be maintained. Notified bodies are also required to perform unannounced audits with their manufacturers.

Additionally, the manufacturer is obliged to implement a system for analysis and reporting of incidents with their device. Any incident that led, might have led, or might lead to the death, temporary or permanent serious deterioration of a patient's, user's or other person's state of health, or to a serious public health threat; must be reported to the competent authority via EUDAMED and to the notified body. Examples of reportable incidents could include software that crashes during a procedure or a critical instruction that was omitted from the user manual.

Moreover, the notified body needs to be informed by the manufacturer in case of substantial changes to a CE-certified medical device or a certified quality management system. For example, if the device's intended use will be extended to serve another patient population or if the manufacturer decides to internalize (part of) the outsourced design and development process, these planned changes are to be submitted to the notified body for assessment. The notified body will assess the proposed changes. In the case of medical device changes, the notified body will decide whether a new technical documentation assessment is required or whether a supplement to the CE-certificate can be provided based on the information provided. In case of a QMS change, it is checked whether an additional audit is required for scope extension.

Conclusion

The EU MDR entails an important impact in terms of time and resources required to obtain regulatory approval of a medical device that also producers of solutions targeting an active and healthy aging through ICT should bear in mind. Given these constraints, as a manufacturer it is essential to be aware of the regulatory requirements as from the concept phase to apply them during the design and development of the solution. Failing to take the regulatory strategy into consideration when preparing the commercialization strategy might lead to substantial delays in placing the product on the market.