GMED LNE GROUP Newsletter

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# QUALIFICATION AND CLASSIFICATION OF MEDICAL DEVICE SOFTWARE UNDER REGULATION (EU) 2017/745

**Over the past decades use of software as a medical device increased exponentially as it undoubtedly helps to improve patient health. In parallel, development and application of regulatory requirements strengthen controls over medical devices specifically medical device software.**
**The European Medical Device Regulations (EU MDR) introduces new classification rules for medical device software. This newsletter will cover qualification and classification of software as medical device under Regulation (EU) 2017/745.**
**Where to start?** For manufacturers who plan to CE mark software under the European Medical Device Regulation, the first step is to determine if the software falls under the definition of medical device per Regulation (EU) 2017/745.

## A MEDICAL DEVICE SOFTWARE DEFINITION UNDER REGULATION (EU) 2017/745

As per Article 2(1) of the EU MDR, Medical device means any instrument [...] **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;
- 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.

## B QUALIFYING A SOFTWARE AS MEDICAL DEVICE

Based on the above definition of medical device, the first step to qualify a software as a medical device is to verify that the software has a **"medical purpose as described by the manufacturer"**.
In addition, if the software does not fall under the definition of medical device but is intended by manufacturer to be used as an accessory for a medical device, it falls under Medical Device European Regulation.

It is necessary to clarify that Softwares for general purposes, even when used in a healthcare setting, or Softwares intended for lifestyle and well-being purposes are not a medical device.

Below are **examples** of software that does not qualify as a medical device although used in healthcare environment:
- Software that is only intended to communicate, store, or perform a simple search;
- Software that is only used for administrative purposes, including workflow or scheduling;
- Software that provides access to literature data;
- Software intended to encourage a healthy lifestyle, such as wellness applications...

Attention should be drawn to softwares that are a combination of different modules, some with and some without medical purpose. As per MDCG 2019-11 guidance, only modules with "medical purpose" are subjected to the Medical Device European Regulation. However based on the general safety and performance requirements 14.1 of Regulation (EU) 2017/745 the whole combination must be safe and must not impair the specified performance of the modules that are subject to the MDR if the modules are intended to be used together. The limits and interfaces of each module are so to be identified.

## C TWO TYPES OF MEDICAL DEVICE SOFTWARE

As per Regulation (EU) 2017/745 a device software falls under one of the below categories:
- Medical device software which is independent of any other device (standalone software);
- Medical device software which is embedded in or a component of the medical device.

In both cases (standalone or embedded) the qualification of software as a medical device is related to its intended medical purpose and is not affected by the location or the type of interconnection between medical device and software.

## D CLASSIFICATION OF SOFTWARE AND ROLE OF IMPLEMENTING RULE

Once software is qualified as a medical device, the next step is to classify the software. The Regulation (EU) 2017/745 addresses classification rules of medical devices in Annex VIII.
As it was already the case with the Medical Device Directive 93/42/EEC, the annex related to classification is structured as follow:
- Definition;
- Implementing rules;
- Classification rules.

Application and consideration of implementing rules are essential to a proper classification of medical devices and specifically software as medical device. Among all implementing rules, rules 3.3 and 3.5 need to be considered when dealing with medical device software, either as a device or as a component of a device. These two implementing rules are defined as follow.

### Implementing rule 3.3

- Software, which **drives a device or influences** the use of a device, shall fall within the **same class as the device**;
- If the software is **independent** of any other device, it shall be **classified in its own** right.

### Implementing rule 3.5

- If several rules, or if, within the same rule, several sub-rules, apply to the same device based on the device's intended purpose, the strictest rule and sub-rule resulting in the **higher classification shall apply.**

## E A SPECIFIC RULE FOR SOFTWARE

One of the novelties of the Regulation (EU) 2017/745 is the introduction of a specific rule, rule 11, for Software. Under Medical Device Directive 93/42/EEC, a software was deemed an active medical device and felt under the same classification rule as the device (rules 9 to 12).

### Why a specific rule for software?

Under the Medical Device Directive 93/42/EEC, the selection of these rules for all active medical devices was directly related to the risk coming from the exchange of energy between the body and the medical device. However, when a software is involved, in most cases, the risk is not related to the software, it is in fact related to the failure to provide correct information. Consequently, and to correctly categorize the harm related to the information provided by an active device, rule 11 was introduced.

### Up classification of Medical device software under Regulation (EU) 2017/745

It is important to note that under Rule 11 any medical device software which is:
- Intended to provide information which is used to take decisions with diagnosis or therapeutic purposes; or
- Intended to monitor physiological processes

is classified as class IIa or higher.

### Rule 11 of Regulation (EU) 2017/745

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**; or
- **A 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**.

Please note that in order to classify active medical devices all active rules (Rules 9, 10, 11, 12, 13, 15 and 22) should be considered and examined.

Per MDCG 2019-11 guidance the above discussed requirements criteria are also applicable to applications which are operated on mobile phone, in the cloud or other platforms.

## Conclusion

To CE mark a software as a medical device under the European Medical Device Regulation (EU MDR), manufacturers of medical software shall undergo qualification and classification based on the intended use of their device. Once qualified as medical device software, manufacturers should consider all classification and implementing rules described under Annex VIII of EU MDR for its classification. An accurate classification facilitates the selection of a proper conformity assessment route in order to enter the European market.

# To go further

### TRAININGS FOR EUROPE AND OTHER PART OF THE WORLD (EXCL. US)

Medical Device Software Life Cycle Processes
SA 36 | 2 day-training session | On demand
→ CONTACT GMED TRAINING CENTER

Technical Documentation under Regulation (EU) 2017/745
SA 43 | 2 days | On demand
→ CONTACT GMED TRAINING CENTER

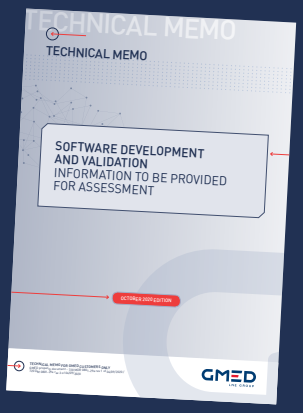
### TRAININGS FOR NORTH AMERICA REGION

European Medical Devices Regulation (EU) 2017/745
2-day training session | On demand
→ CHECK OUT THE PROGRAM

Medical Device Electrical Safety – IEC 60601-1 3rd Edition (Ed3.1) and Introduction to Electromagnetic Compatibility (EMC) Requirements
2 day-training session | On demand
→ CHECK OUT THE PROGRAM

### TECHNICAL MEMO
**Software development and validation**

[ONLY FOR GMED CUSTOMERS]




To address the regulatory requirements, software development and software validation are subject to assessment.
The assessment of software development is conducted according to the IEC 62304 standard "Medical device software - Software life cycle processes".
The GMED teams have prepared this memo to specify the elements to be provided for assessment of software development and software validation.
We invite you to explore and benefit from this technical memo.

→ REQUEST THE TECHNICAL MEMO FROM YOUR CERTIFICATION PROJECT MANAGER

## Newsletter

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