



COCIR Contribution

Decision diagram for qualification of software as medical device

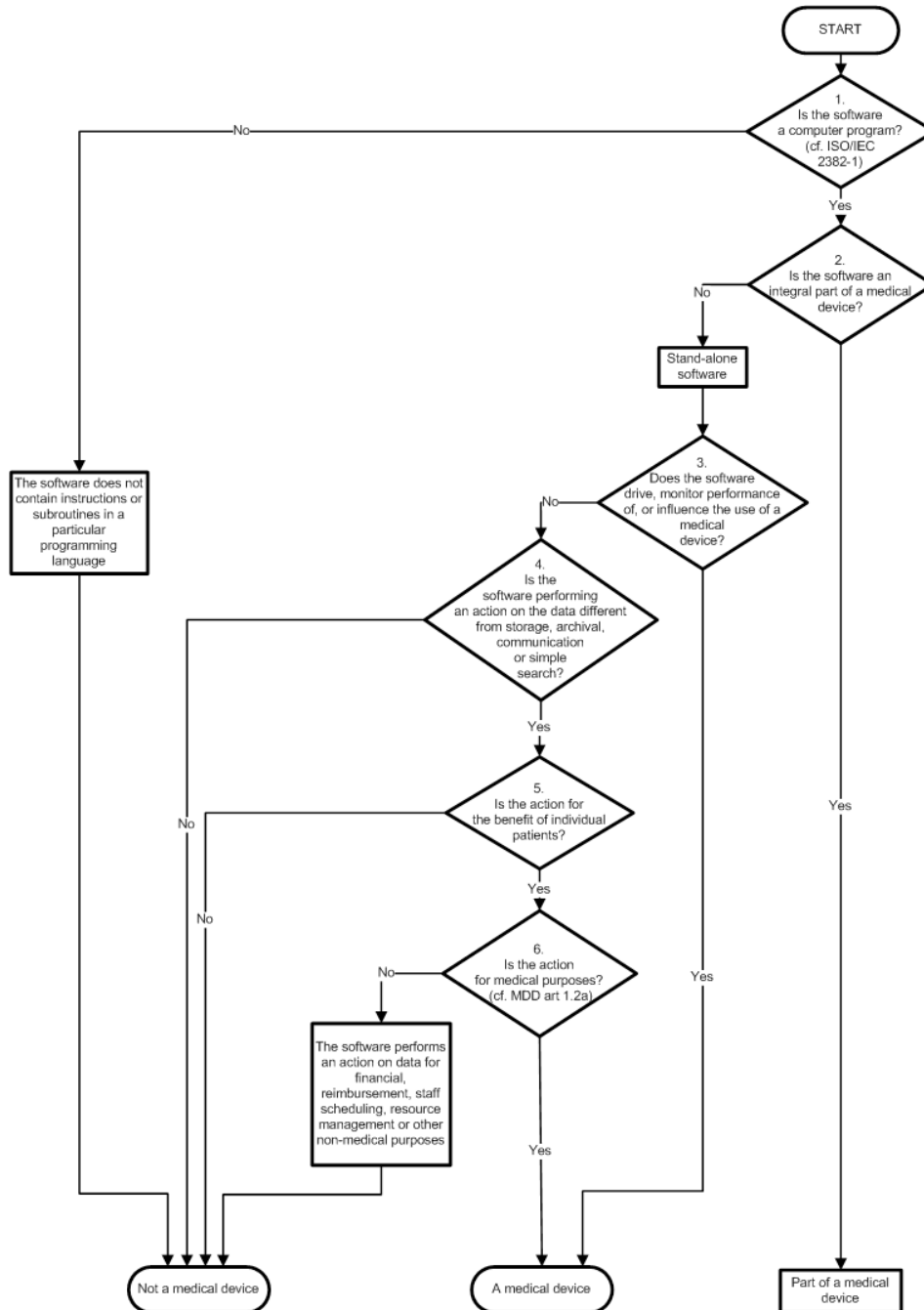


Figure 1. Diagram to assist qualification of software as medical device. The following text explains each decision step.

The above diagram (Figure 1) outlines the process used to determine if software used in the medical domain qualifies as a medical device subject to the requirements of European Directive 93/42/EEC.

Decision step 1: if the software is a *computer program*¹, then it could be a medical device. If the software is not a computer program, then it is a digital document and therefore not a medical device.

Examples of computer programs are software applications, text files and spreadsheets with macro's, actions, scripts, dynamically linked libraries, batch files, style sheets and any document containing active formatting or filtering instructions. Examples of digital documents are image files, DICOM files, digital ECG recordings, numerical results from IVD-tests such and electronic health records (EHR).

Remark: While the EHR is usually not a computer program, the EHR system, i.e. the software writing, retrieving, representing, etc. the information in the EHR, is a computer program. This is similar as for DICOM files and PACS.

Decision step 2: if the software is an integral part of medical equipment, it is a part of a medical device rather than a medical device in its own right or an accessory to a medical device. In the regulatory process, therefore, the software must be considered as part of that medical device.

Decision step 3: if the software drives, monitors performance of, or influences a medical device, it is a medical device or an accessory to a medical device, in which case it is to be treated as a medical device, thus subject to CE marking.

Decision step 4: If the software does not perform an action on data, or performs an action limited to storage, archival, communication² or simple search³ it is not a medical device. In other cases, including where the software alters the representation of data for a medical purpose, it could be a medical device.

Examples of actions which could qualify the software as a medical device are reconstruction, compression, filtering, pattern recognition, modelling, interpolation, transformation, classification, segmentation, registration, calculations, quantification, qualification, rendering, visualisation, interpretation, etc.

Altering the representation of data for embellishment or usability purposes does not make the software a medical device. If such alterations are made to facilitate the perception and interpretation tasks performed by the radiologist or clinician when interpreting the image or data, e.g. by transposing data from a table into a graph, or when searching the image for findings that support a clinical hypothesis as to the diagnosis or evolution of therapy, the software could be a medical device. Note that the display of images usually involves alterations to the representation because techniques are used such as contrast stretching, edge enhancement, gray scale manipulation, smoothing, sharpening, zooming and re-sizing.

Decision step 5: If the software performs an action on data for the benefit of individual patients, whether or not anonymized (such as for an independent second opinion), it could be a medical device. If the software does not perform an action on data for individual patients, it is not a medical device.

An example of software for the benefit of individual patients is software intended to evaluate data of the patient to support or influence the healthcare delivery of that patient.

¹ A computer program is defined as syntactic unit that conforms to the rules of a particular programming language and that is composed of declarations and statements or instructions needed to solve a certain function, task, or problem. Source: ISO/IEC 2382-1:1993 (01.05.01) Information technology -- Vocabulary -- Part 1: Fundamental terms

² Communication: The flow of information from one point, known as the source, to another, the receiver; Source: IEEE 610.10-1994

³ Simple search refers to the retrieval of records by matching record metadata against record search criteria. Simple search is not to be interpreted as to identify, mark, highlight, or in any other manner direct attention to portions of record data or portions of record images that match the search criteria.

Examples of software not for the benefit of individual patients are software aggregating population data, software providing generic diagnostic or treatment pathways, scientific literature, medical atlases, models and templates as well as software for epidemiologic studies or registers.

Decision step 6: if the software performs an action on data (related to individual patients) and the manufacturer of the software has intended this specifically for medical purposes⁴, then the software qualifies as a medical device. If the software does not have a medical purpose as intended by the manufacturer, such as invoicing or staff planning (even if this is for individual patients), it is not a medical device.

Note: tasks such as e-mailing, web- or voice messaging, data parsing, word processing, data administration and back-up always serve other goal(s). These tasks should not be considered to be a purpose in themselves. Such tasks may be intended for general purposes, e.g., to comply with legal requirements on data retention or when a patient requests his personal data (often provided on a DVD with a DICOM viewer) or may have a more specific purpose such as staff planning or resource scheduling.

⁴ Software intended by its manufacturer to be used for human beings specifically for the following purposes is considered to have a medical purpose:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception.

Extracted from European Directive 93/42/EEC, Article 2a