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Original
Medical Device Software: From Requirements to Certification / Giordano, N., Rosati, S., Balestra, G.. - ELETTRONICO. - 309:(2023), pp. 139-140. (Special Topic Conference (STC2023) Torino (Ita) 25 - 27 October 2023) [10.3233/SHTI230760].

Availability:
This version is available at: 11583/2984533 since: 2025-04-23T10:22:05Z

Publisher:
IOS Press

Published
DOI:10.3233/SHTI230760

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29 November 2026

Telehealth Ecosystems in Practice
M. Giacomini et al. (Eds.)

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doi:10.3233/SHTI230760

Medical Device Software: From Requirements to Certification

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Abstract. The role of software in healthcare is getting more and more pervasive. Nevertheless, manufacturers sometimes forget that these software are medical devices and must be certified according to the EU Medical Device Regulation 2017/745. In this work we propose a pipeline for developing a Medical Device Software (MDS) compliant with the regulations and certifiable. The pipeline includes the phase of requirements elicitation, risk assessment and analysis of effectiveness as key elements. The preparation of the technical file should be carried out in parallel with the MDS development. In the overall, it can be stated that the certification process starts with the conceptualization of the MDS and proceeds all along its design and implementation.

Keywords. Medical device software, MDS certification

1. Introduction

Digital healthcare is based on medical software to computerize clinical processes, support telemedicine services, use Apps for patients care, improve care with decision aid systems.

Most of these software are medical devices and must be certified following the EU Medical Device Regulation 2017/745. The new regulation has specific rules for Medical Device Software (MDS) and more attention is placed on the certification process of these devices than in the past. In 2019, the EU working group has issued a specific guide for the qualification of a software as a MDS, and several standards and norms are available. Medical Device software (MDS) development consists of several steps and requires different competencies.

2. MDS development steps

Figure 1 highlights the steps to be performed for developing a MDS and how the technical report will document all the steps.

Requirements elicitation is fundamental to ensure the definition of the correct specifications and that the software is in agreement with the sequence of the processes'

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activities. Process modeling tools may support this step. Another important issue is safety. Risk analysis must be performed during the design phase and during the entire life cycle of the product.

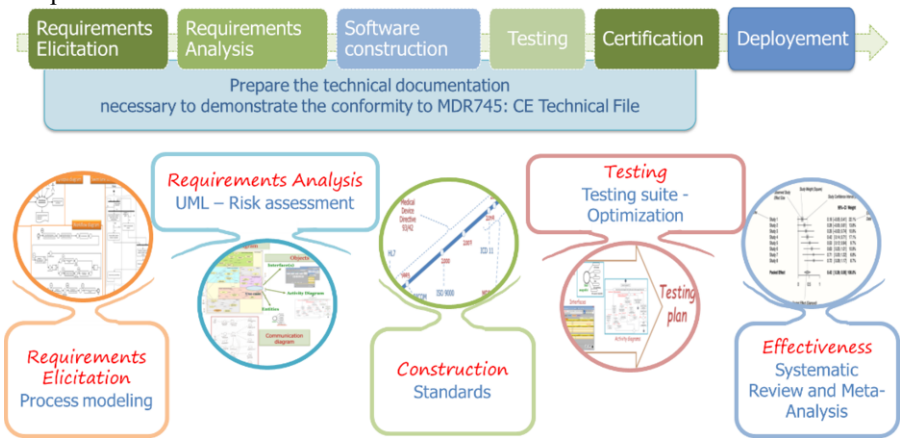


Figure 1. Graphical representation of the process to design a MDS compliant with the Medical Device Regulation 2017/745 and thus certifiable

MDS safety must be evaluated both in terms of cybersecurity (because it is a software) following the specific guidelines and in terms of hazards for the physical person (because it is a medical device) [1,2] following ISO/TR 24971 (2020) guidance. When the MDS is ready, its effectiveness must be proved. Systematic literature review and meta-analysis are used during this step to compare the novel MDS with similar devices. For some devices, like decision aid systems, specific trials are performed [3]. MDS construction may benefit of UML standard both for Requirements analysis and structured testing. As testing is a time-consuming activity, optimization techniques may be used to build the test suite.

3. MDS certification process

The certification process requires the construction of a technical report. The class of the device is decided using the MDR rules. If the class is greater than I, a notified body must review all the documentation, including the technical report, to obtain the certification.

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