UDecide

MANAGEMENT OF ISO 62304   
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SCOPE: This document contains the projects interpretation and management of the standard: ISO 62304:2006.

REFERENCES:

REVISION HISTORY:

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| **Revision** | **Revised by** | **Revision date** | **Description of changes** |
| 1.0 | Sofie Bjørn | 31-03-2021 | First version of interpretation and management of the standard: ISO 62304:2006. |
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APPROVAL:

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|  | *Name and job function* | *Signature* | *Date* |
| *Author:* |  | | |
| *Reviewer:* |  | | |
| *Independent reviewer:* |  | | |

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| **Where in**  **ISO 62304: 2006** | **What the chapter/article is about** | **Our interpretation and management of the regulation** | **Reference to other standards/documents/annexes** |
| Chapter 3: | Terms and definition |  |  |
|  | 3.12 Medical device software | “Software system that has been developed for the purpose of being incorporated into the medical device being developed or that is intended for use as a medical device in its own right.” |  |
|  | 3.22 Security | “Protection of information and data so that unauthorized people or systems cannot read or modify them and so that authorized persons or system are not denied access to them.” |  |
|  | 3.25-3.28 | Software item, product, system and unit is defined differently.   * Unit: unable to further subdivide * Item: identifiable part of a program * Product: set of computer programs, procedures and documentation * System: integrated collection of items to accomplish a specific function(s). |  |
| Chapter 4 | General requirements |  |  |
|  | 4.1 QMS | Shall demonstrate ability to provide MDS that meets requirements. |  |
|  | 4.2 Risk management | Shall have a risk management process complying with ISO standards | ISO 14971 -  Risk |
|  | 4.3 Software safety classification | Class A: no injury or damage to health is possible  Class B: Non-serious injury is possible  Class C: Death or serious injury is possible.  If software is divided it is possible to have different classifications, however referring to the system as a whole will require using the highest classification.  Until classification is assigned, the rules of classification C shall apply. |  |
| Chapter 5 | Software development process |  |  |
|  | 5.1.  SW development planning | Manufacturer shall have a plan for the development process. This has to include the processes, traceability between requirement (system and sw), test and risk control. The safety classification sets out which rules apply and thus which requirements must be handled. SInce our software is class A, the following is also required:  The plan shall be updated, and include references to the system requirements.  Planning of verification process, risk management, documentation,  5.1.9 Software configuration management planning - ?? | Is quite similar to QMS og RMS. |
|  | 5.2 Software requirements analysis | From the system requirements we shall define software system requirements. These are probably identical since the software is a stand alone device.  The terms must be eligble for re-evaluation (predefined) non-ambiguous and traceable to the system  requirements. |  |
|  | 5.5 Software unit implementation and verification | We shall implement every software unit.  Because it is a class A safety classification we do not have to document or evaluate any of the verification processes. |  |
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