International Certified Professional for Medical Software Board e.V.

# Certified Professional for Medical Software

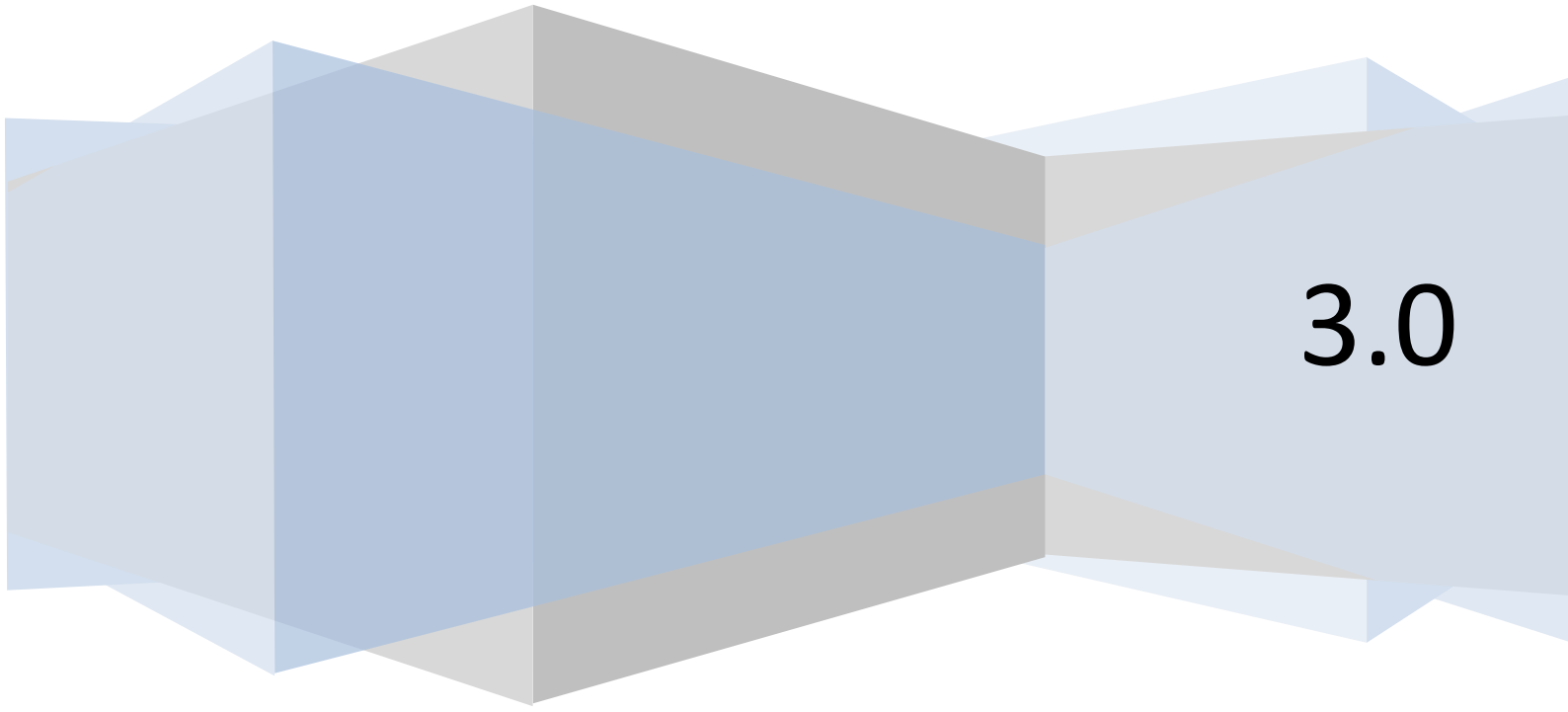
## Curriculum

### Foundation Level

### Advanced Level Process Management

### Advanced Level Software Development

Version 3.0 / 2020-10-15



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Substantial revisions of the curriculum in Version 2.0 are the result of a project of the medical technology top cluster of Medical Valley EMN funded by the Federal Ministry of Education and Research (BMBF) (project numbers: 13EX1013A, 13EX1013H and 13EX1013K).

Version 2.1 contains only editorial changes and minor corrections compared to version 2.0.

Version 3.0 has been completely revised on the basis of new guidelines and adapted to changes in the regulations. In addition, the topic of IT security has been added and the display format has been changed.

# Change history

| DATE | CHANGE | AUTHOR |
|---|---|---|
| **2010-10-12** | Initial version | ICPMSB e.V. |
| **2011-10-11** | Addition of a mapping of the chapters of the textbook | ICPMSB e.V. |
| **2011-11-17** | More detailed listing of the learning objectives | ICPMSB e.V. |
| **2015-10-26** | Version 2.0 after adoption of the results of the funded project | ICPMSB e.V. |
| **2016-07-16** | Release of Version 2.0 | ICPMSB e.V. |
| **2020-10-15** | Release of Version 3.0<br>Completely revised version in accordance with new guidelines and taking into account changes in regulation. Addition of the topic “IT security”. The presentation format has been changed. | ICPMSB e.V. |

# Table of contents

# Introduction

The present curriculum is the result of a project of the medical technology top cluster of Medical Valley EMN funded by the Federal Ministry of Education and Research (BMBF) (project numbers: 13EX1013A, 13EX1013H and 13EX1013K) and of the revision of the hitherto valid "Certified Professional for Medical Software" curriculum (CPMS; Version 1.1).

In CPMS Foundation Level (abbreviated in the following with FL), the fundamentals of the development of medical software are taught.

In CPMS Advanced Level Process Management (abbreviated in the following with AL-PM), contents relating to the subjects process design, regulatory affairs and quality management are taught in greater depth.

In CPMS Advanced Level Software Development (abbreviated in the following with AL-SW), contents relating to the development of medical software are taught in greater depth.

The curriculum is structured into six modules, the sequence of which is not arbitrary. An overview of the times is provided at the beginning of each module. Learning objectives are assigned to each subsection. Each learning objective is assigned to one of the following cognitive levels:

- C1: remembering
- C2: understanding
- C3: applying

Cognitive level C4 (analysing) is not required.

The entry "R" requires that the contents of the Foundation Level be repeated in Advanced Level.

Notice for training course providers: C2 learning objectives must be taught based on examples. For C3 learning objectives, an exercise is required.

The students must only be able to recite (C1) the terms named in the paragraph directly below the title if this is explicitly indicated in the learning objectives.

# 1. Regulatory fundamentals curriculum

| chapter | ID | Learning objective | *explanation* | FL | AL | Reference to Curriculum 2.0 |
|---|---|---|---|---|---|---|
| **1** | | **Regulatory fundamentals** | | | | |
| **1.1** | | **Legal basis** | | | | |
| **1.1.1** | | **Terms and agents** | | | | |
| | 1 | To know how a medical device is defined in Europe. | *Definition per MDR* | C1 | - | M1-LE1.1-1-1 |
| | 2 | To understand when software is a medical device. | *Component of a medical device, accessory, software as a medical device* | C2 | - | M1-LE1.1-2-1 |
| | 3 | To know the definition of the term "clinical benefit." | *Definition per MDR* | C1 | | new |
| | 4 | To understand that a "positive impact on patient management" is also considered a clinical benefit. | *Delayed or no treatment may pose a hazard.* | - | C2 | new |
| | 5 | To know what an "economic agent" is. | *Definition per MDR* | C1 | - | new |
| | 6 | To know the definition of the "manufacturer," "authorized representative," "importer," and "dealer" roles. | *Definition per MDR* | - | C1 | new |
| | 7 | To know how "systems" and "treatment units" are defined. | *Definition per MDR* | - | C1 | new |
| | 8 | To know when systems and treatment units are to be handled as new medical devices. | *TBD* | C1 | - | new |
| **1.1.2** | | **Legal basis in Europe** | | | | |

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| | 9 | To know the difference between EU Directives and EU Regulations. | *Indirect influence via national law vs. direct influence.* | C1 | - | M1-LE1.2-1-1. |
| | 10 | To know the essential objectives of European directives and regulations. | *Dismantling of trade barriers, comparable quality standards.* | C1 | - | M1-LE1.2-1-1. |
| | 11 | To know what a "common specification" is. | *"Back door" for further requirements* | C1 | - | new |
| | 12 | To understand the meaning of "common specifications." | *TBD* | - | C2 | new |
| | 13 | To know the relevant process standards for medical devices. | *ISO 13485, ISO 14971, IEC 62304, IEC 62366* | C1 | - | M1-LE1.2-2-1. |
| | 14 | To understand the meaning of harmonized standards. | *Principle of presumption* | C2 | - | M1-LE1.2-2-1 |
| | 15 | To know that there are national standardization bodies that translate international standards. | *e.g., ISO vs. DIN EN* | - | C1 | M1-LE1.2-2-1 |
| | 16 | To know how a standard becomes a harmonized standard. | *Official Journal of the EU* | C1 | - | M1-LE1.2-2-1 |
| | 17 | To know which national laws implement the provisions of the EU. | *Depends on the country* | - | C1 | M1-LE1.2-3-1. |
| | 18 | To understand the correlations between the harmonized standards and the EU provisions and among the harmonized | *Formerly "regulatory map"* | C2 | - | M1-LE1.2-4-1. . |

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| | | standards themselves. | | | | |
| **1.2** | | **European Regulations** | | | | |
| **1.2.1** | | **Medical Device Regulation (MDR)** | | | | |
| | 1 | To know the structure of the MDR. | *Chapter structure, annexes* | C1 | - | M1-LE2.1-1-1. |
| | 2 | To know the term "essential requirements." | *Historically, Annex I to the MDD.* | C1 | - | M1-LE2.1-2-1. |
| | 3 | To understand the importance of Annex I to the MDR. | *Safety and performance requirements, formerly "essential requirements"* | C2 | - | M1-LE2.1-2-1 |
| | 4 | To know the essential tasks of a manufacturer. | ** Ensure the conformity of the devices*<br>** Implement a risk management strategy*<br>** Conduct a clinical evaluation*<br>** Create and maintain technical documentation*<br>** Create a declaration of conformity and apply the CE marking*<br>** Fulfill the UDI requirements*<br>** Ensure adequate financial coverage of their potential liability* | C1 | - | new |
| | 5 | To know that each manufacturer of a medical device must establish a QM system. | *Essential precondition for regulated procedures and assured quality, therefore also essential precondition for the production of safe devices.* | C1 | - | new |
| | 6 | To know that each manufacturer of a medical device must designate a "Person responsible for | *See MDR Article 15.* | C1 | - | new |

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| | | regulatory compliance." | | | | |
| | 7 | To know the tasks of a "Person responsible for regulatory compliance." | *See MDR Article 15.* | - | C1 | new |
| | 8 | To know that the consideration of IT security forms a part of the general safety and performance requirements. | *In greater focus due to increasing interconnectedness of devices.* | C1 | - | new |
| | 9 | To know the essential tasks of an authorized representative. | ** Ensure that a declaration of conformity and technical documentation are available and that a corresponding conformity assessment has been conducted*<br>** Provide a copy of the documents described above*<br>** Comply with the registration requirements*<br>** Verify that the manufacturer is in compliance with the registration requirements*<br>** Cooperate with authorities by providing all requested documents and information*<br>** Forward complaints and reports of suspected incidents immediately to the manufacturer* | - | C1 | new |

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| | 10 | To know the essential tasks of an importer. | ** Verify that the device has the CE marking and a declaration of conformity exists*<br>** Verify that the manufacturer is known and has designated an authorized representative*<br>** Verify that the devices are labeled according to the Regulation and an instructions for use leaflet is enclosed*<br>** Verify that a UDI has been assigned, as applicable*<br>** Specify their contact details on the device or package*<br>** Verify that the device is registered and add additional information*<br>** Ensure adequate storage and transport conditions*<br>** Forward complaints concerning the device to the manufacturer and the authorized representative*<br>** Retain a copy of the declaration of conformity*<br>** Cooperate with authorities by providing all requested documents and information* | - | C1 | new |
| | 11 | To know the essential tasks of a dealer. | ** Verify that the necessary accompanying documents and information are enclosed with the device*<br>** Verify, in the case of imported devices, whether the importer has fulfilled its obligations*<br>** Verify whether a UDI* | - | C1 | new |

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| | | | *has been assigned, as necessary*<br>** Ensure adequate storage and transport conditions while the device is under the responsibility of the dealer*<br>** Communicate with the manufacturer, authorized representative, importer, and authorities in the case of potential incidents*<br>** Cooperate with authorities by providing all requested documents and information* | | | |
| 1.2.1.1. | | Product classification | | | | |
| | 12 | To know the classes into which medical devices are categorized. | *I, Im, Is, Ir, IIa, IIb, III* | C1 | - | M1-LE2.1-4-1 |
| | 13 | To understand the rules of product classification. | *Basic principle only* | C2 | - | M1-LE2.1-4-1. |
| | 14 | To be able to apply the rules of product classification for software in an example. | *With exercise* | - | C3 | M1-LE2.1-4-1 |
| 1.2.1.2. | | Accessories and custom-made devices | | | | |
| | 15 | To know what an accessory is. | *Definition per MDR* | C1 | - | M1-LE2.1-5-1 |
| | 16 | To understand why it may be useful to declare software as an accessory. | *Independent classification* | - | C2 | new |
| | 17 | To know what a custom-made device is. | *Definition per MDR* | - | C1 | M1-LE2.1-5-1 |
| | 18 | To know the requirements | *TBD* | - | C1 | M1-LE2.1-5-1 |

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| | | that apply to custom-made devices. | | | | |
| 1.2.1.3. | | Technical documentation | | | | |
| | 19 | To understand the importance of the technical documentation. | *Proof, precondition for declaration of conformity* | C2 | - | M1-LE2.1-6-1 |
| | 20 | To know the typical contents of the technical documentation. | *This learning objective does not require complete knowledge of Annex II to the MDR, but instead merely a basic understanding. This includes knowledge of at least the following:*<br>** Product description*<br>** Intended purpose*<br>** Classification*<br>** Applicable standards*<br>** Proof of compliance with the essential requirements*<br>** Risk analysis*<br>** Design drawings*<br>** Test results*<br>** Instructions for use leaflet*<br>** Product label*<br>** Clinical evaluation*<br>** Declaration of conformity* | C1 | - | M1-LE2.1-6-1 |
| | 21 | To know the contents of the technical documentation. | *See Annex II to the MDR.* | - | C1 | M1-LE2.1-6-1 |
| | 22 | To know that the technical documentation for a medical device must be updated regularly depending on its class. | *See Annex III to the MDR.* | C1 | - | new |
| 1.2.1.4. | | Conformity assessment procedure | | | | |
| | 23 | To understand the principle of | *Procedure based on annexes to the MDR,* | C2 | - | M1-LE2.1-7-1 |

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| | | the conformity assessment. | *participation of notified bodies.* | | | |
| | 24 | To know which options exist for the conformity assessment per MDR. | *Per the annexes to the MDR.* | C1 | - | M1-LE2.1-7-1 |
| | 25 | To understand the different conformity assessment procedures for medical devices. | *Per the annexes to the MDR.* | - | C2 | M1-LE2.1-7-1 |
| | 26 | To understand the impact of product classification on the conformity assessment procedure. | *Limited selection, depending on class.* | C2 | - | M1-LE4.1-5-1 |
| | 27 | To understand why only one conformity assessment procedure is advisable for software. | *Either nothing at all (for class I, which hardly exists anymore) or a complete quality assurance system. Other procedures are usually not possible/unaffordable.* | - | C2 | M1-LE4.1-5-1 |
| | 28 | To understand the workflow of a conformity assessment procedure. | *TBD* | - | C2 | M1-LE4.1-6-1 |
| | 29 | To understand the significance of the CE mark for the European market. | *Ensure self-labeling in conformity with the statutory requirements to the best of one's knowledge and belief.* | C2 | - | M1-LE2.1-8-1 |
| 1.2.1.5. | | Eudamed and UDI | | | | |
| | 30 | To understand the purpose of the UDI system. | *Traceability of devices* | C2 | - | new |
| | 31 | To know how a UDI is structured and where it must be affixed. | *TBD* | - | C1 | new |
| | 32 | To know that a European database for | *Eudamed* | C1 | - | new |

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| | | medical devices exists. | | | | |
| | 33 | To understand the significance of the European database for medical devices. | *Transparency for end users, better control of manufacturers.* | - | C2 | new |
| | 34 | To know the contents of the European database for medical devices. | | - | C1 | new |
| 1.2.1.6. | | Monitoring and vigilance | | | | |
| | 35 | To know the difference between "post-market surveillance," "vigilance," and "market surveillance." | *Per MDR* | C1 | - | new |
| | 36 | To know the essential obligations of a manufacturer concerning post-market surveillance. | ** Create a post-market surveillance plan*<br>** Collect data actively and systematically*<br>** Create a surveillance report (class I devices)*<br>** Create a "safety report" regularly (class IIa and higher)* | - | C1 | M1-LE4.1-11-1 |
| | 37 | To know the essential obligations of a manufacturer concerning vigilance. | ** Report serious incidents to the authorities*<br>** Analyse serious incidents*<br>** Report safety corrective actions to the authorities prior to implementation*<br>** Identify and report significant trends involving non-serious incidents* | | C1 | new |
| **1.2.2** | | **Other EU requirements** | | | | |
| 1.2.2.1. | | In vitro diagnostics | | | | |
| | 38 | To know the definition of an in vitro diagnostic medical device. | *Definition per MDR* | C1 | - | M1-LE2.2-1-1 |

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| | 39 | To know that there are separate requirements that apply to in vitro diagnostic medical devices. | *IVDR, classification by lists* | C1 | - | M1-LE2.2-2-1 |
| | 40 | To know the structure and contents of the IVDR. | *Chapter structure, annexes* | - | C1 | M1-LE2.2-1-1 |
| | 41 | To understand the conformity assessment procedure options for in vitro diagnostic medical devices. | *TBD* | - | C1 | M1-LE2.2-2-1 |
| 1.2.2.2. | | Active implantable medical devices | | | | |
| | 42 | To know the definition of an active implantable medical device. | *Definition per MDR* | C1 | - | M1-LE2.3-1-1. |
| | 43 | To know that active implantable devices are covered by the MDR. | *as opposed to formerly (AIMDD)* | C1 | - | new |
| | | - | | | | M1-LE2.3-2-1 |
| **1.2.3** | | **Implementation in national law** | | | | |
| | 44 | To know that there are national requirements in addition to EU Regulations. | *German examples: German Medical Device Act [MPG] + German regulations/ordinances* | C1 | - | M1-LE2.4-2-1 |
| | 45 | To know the national provisions for the implementation of European requirements. | *Country-specific, to be defined by the training provider* | n.a. | n.a. | M1-LE2.4-1-1 |
| **1.3** | | **The harmonized standards** | | | | |
| **1.3.1** | | **EN ISO 13485** | | | | |

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| | 1 | To know the scope of application of ISO 13485. | *QMS, medical technology, NOT SW-specific* | C1 | - | M1-LE3.1-1-1 |
| | 2 | To understand the significance of quality management for medical devices. | *Good processes result in good products, basic precondition for everything, related to conformity assessment procedure.* | - | C2 | new |
| **1.3.2** | | **EN ISO 14971** | | | | |
| | 3 | To know the scope of application of ISO 14971. | *Risk management, medical technology, NOT SW-specific* | C1 | - | M1-LE3.2-1-1 |
| | 4 | To understand the significance of risk management for medical devices. | *Risk-based approach, safety is the highest priority.* | - | C2 | M1-LE3.2-1-1 |
| **1.3.3** | | **EN 62304** | | | | |
| | 5 | To know the scope of application of EN 62304. | *SW lifecycle, medical technology* | C1 | - | M1-LE3.3-1-1 |
| | 6 | To understand the significance of the software lifecycle for medical devices. | *Survey in IEC 62304* | - | C2 | M1-LE3.3-1-1 |
| | 7 | To know that in the case of certification audits according to the ISO 13485 standard, an IEC 62304-compliant development process, applying risk management according to ISO 14971, must already exist if the company develops medical software. | | C1 | - | |
| **1.3.4** | | **EN 62366-1** | | | | |

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| | 8 | To know the scope of application of EN 62366-1. | *Usability, medical technology, NOT SW-specific* | C1 | - | M1-LE3.4-1-1 |
| | 9 | To understand the significance of the usability of medical devices. | *Safety-critical, sales argument.* | - | C2 | M1-LE3.4-1-1 |
| | 10 | To understand the correlation between EN 60601-1-6 and EN 62366-1. | *Normative reference, both remain valid, different terms (keyword PEMS)* | - | C2 | M1-LE3.4-2-1 |
| **1.3.5** | | **The EN 60601-x family of standards** | | | | |
| | 11 | To understand that there are other standards harmonized with the EN 60601-x family of standards that must be considered. | *e.g., 60601-1-14 for PEMS and all kinds of device-specific regulations* | C1 | - | new |
| | 12 | To know the scope of application of the EN 60601-x family of standards. | *Programmable electrical medical systems with an applied part* | - | C1 | M1-LE3.5-1-1 |
| | 13 | To know the structure of the EN 60601-x-y family of standards. | *Basic standard, supplementary standards, special regulations* | - | C1 | M1-LE3.5-2-1 |
| | 14 | To know which parts of the EN 60601-x-y family of standards must be applied to the software development process. | *60601-1-14 (PEMS), 60601-1-6 (usability), others depending on device* | - | C1 | M1-LE3.5-3-1 |
| **1.4** | | **Controls** | | | | |
| **1.4.1** | | **Controls during the lifecycle of a medical device** | | | | |

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| | 1 | To know the lifecycle of a medical device from the regulatory standpoint. | ** Intended medical purpose and intended use*<br>** Determination of applicable directives*<br>** Classification*<br>** Determination of conformity assessment procedure*<br>** Implementation of conformity assessment procedure*<br>** Clinical evaluation*<br>** Declaration of conformity and CE marking*<br>** Registration of a medical device*<br>** Placement on the market*<br>** Market surveillance and reporting of incidents* | C1 | - | M1-LE4.1-1-1 |
| | 2 | To know the difference between intended medical purpose and intended use. | *Intended use covers medical standpoint and other use cases.* | C1 | - | M1-LE4.1-2-1 |
| | 3 | To be able to identify the directives and regulations applicable to a device. | *With exercise* | - | C3 | M1-LE4.1-3-1 |
| | 4 | To know the differences in the classification of in vitro diagnostic medical devices and medical devices. | *Completely different procedures are applied - classification by criteria (MDR) and classification by lists (IVDR).* | - | C2 | M1-LE4.1-4-1 |
| | 5 | To understand the purpose and possible forms of a clinical evaluation. | *Proof of medical benefit, from literature route to clinical study, also for software since MDR.* | C2 | - | M1-LE4.1-7-1 |
| | 6 | To know the requirements of the MDR for the | *TBD* | - | C1 | new |

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| | | clinical evaluation of SW. | | | | |
| | 7 | To understand the significance of a declaration of conformity. | *Product is safe according to the manufacturer, post-production phase is added, signatory is responsible, then CE marking can be affixed.* | C2 | - | M1-LE4.1-8-1 |
| | 8 | To know the contents of a declaration of conformity. | *See MDR, Annex IV.* | - | C1 | M1-LE4.1-8-1 |
| | 9 | To know that a medical device must be registered before placement on the market. | *TBD, name differences in the DACH region in relation to EUDAMED.* | C1 | - | new |
| | 10 | To know how and where a medical device must be registered. | *TBD* | - | C1 | M1-LE4.1-9-1 |
| | 11 | To understand the significance of placing a medical device on the market. | *TBD* | C2 | - | M1-LE4.1-10-1 |
| | 12 | To understand the difference between placement on the market and commissioning. | *TBD* | - | C2 | new |
| **1.4.2** | | **Surveillance by authorities and notified bodies** | | | | |
| | 13 | To know the steps of a conformity assessment procedure, in which a notified body must participate. | *TBD (in detail)* | - | C1 | M1-LE4.2-2-1 |
| | 14 | To know that periodic audits take place within a | *With brief explanation of what that means for the manufacturer.* | C1 | - | M1-LE4.2-3-1 |

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| | | certified quality management system. | | | | |
| | 15 | To understand the workflow and objective of an external audit. | *TBD* | - | C2 | new |
| | 16 | To understand the committees and associations as sources of helpful documents. | *TEAM-NB, IMDRF, formerly also GHTF potentially others* | C1 | - | M1-LE4.2-5-1 |
| **1.5** | | **Regulations outside the EU** | | | | |
| **1.5.1** | | **Regulatory fundamentals for the US market** | | | | |
| 1.5.1.1. | | Statutory requirements in the US | | | | |
| | 1 | To know that all products in the US must be approved an one authority, the FDA (Food and Drug Administration). | *(self-explanatory)* | C1 | - | M1-LE5.1-4-1 |
| | 2 | To know that the competent authority for medical devices in the US has police powers. | *(self-explanatory)* | C1 | - | M1-LE5.1-4-1 |
| | 3 | To know the tasks of the FDA. | *Protection and improvement of public health* | - | C1 | M1-LE5.1-4-1 |
| | 4 | To know the structure of American legislation. | *Constitution, legislation (FFDCA), administrative law (21CFR)* | - | C1 | M1-LE5.1-1-1 |
| | 5 | To know the parts of the Federal Food, Drug, and Cosmetic Act that are of significance for manufacturers | *Chapter 5, Sections 505-1, 510, 513, 515, 522* | - | C1 | M1-LE5.1-2-1 |

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| | | of medical devices. | | | | |
| | 6 | To know which part of CFR Title 21 requires a quality management system comparable to ISO 13485. | *21 CFR 820* | - | C1 | M1-LE5.1-3-1 |
| | 7 | To understand what is involved in 21 CFR Part 11. | *Electronic records, electronic signatures hybrid solutions essential requirements* | - | C2 | new |
| 1.5.1.2. | | Classification and approval in the US | | | | |
| | 8 | To know the legal basis for the classification of medical devices on the American market. | *FFDCA 513* | - | C1 | M1-LE5.2-1-1. |
| | 9 | To know the procedure for classification of a medical device in the US. | *Per 21 CFR 862-892* | - | C1 | M1-LE5.2-2-1. |
| | 10 | To understand the difference among the various approval procedures in the US. | *TBD* | - | C2 | new |
| | 11 | To know the required activities and documents for approval of class I and II medical devices. | *TBD* | - | C1 | M1-LE5.3-1-1 |
| | 12 | To know the activities and the scope of the approval of a class III medical device. | *TBD* | - | C1 | M1-LE5.3-2-1. |
| 1.5.1.3 | | FDA guidance documents | | | | |
| | 13 | To understand the significance | *Tools for auditors and manufacturers* | - | C1 | new |

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| | | of the FDA guidance documents. | | | | |
| | 14 | To know which FDA guidance documents are relevant for medical software. | *General Principles of SW Validation, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Off-The-Shelf Software Use in Medical Devices and new guidance documents on cybersecurity, AI, and other topics* | - | C1 | M1-LE5.4-1-1<br>M1-LE5.4-2-1<br>M1-LE5.4-3-1<br>M1-LE5.4-4-1 |
| | 15 | To know that the software-specific requirements that apply to medical devices in the regulatory jurisdiction of the FDA are not covered by law, but rather by guidance documents. | *Primarily by the "General Principles of SW Validation" document* | - | C1 | M1-LE5.4-1-1 |
| | 16 | To understand what the FDA means by "software validation" (as set forth in its guidance). | *Clear-cut SW development* | - | C2 | M1-LE5.4-2-1 |
| | 17 | To understand the "level of concern" concept for medical software. | *Minor, moderate, major classification using decision tree* | - | C1 | M1-LE5.4-3-1 |
| | 18 | To know the level of documentation of software development required by the FDA. | *Per "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"* | - | C1 | M1-LE5.4-1-1 |
| 1.5.1.4 | | The FDA SW Pre-Certification | | | | |

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| | | Program (Pre-Cert) | | | | |
| | 19 | To understand the basic idea of the SW Pre-Certification Program (Pre-Cert) of the FDA. | *Mature organizations have clean operations and are not required to be reviewed as strictly during the approval process, at least for class I devices.* | - | C2 | new |
| | 20 | To know the "organizational excellence" requirements that apply to manufacturers. | *TBD* | - | C1 | new |
| **1.5.2.** | | **Approval procedures in other countries** | | | | |
| | 21 | To know that Health Canada is responsible for the approval of medical devices in Canada. | *Health Canada is an authority, to which the manufacturer submits the documents for the approval.* | - | C1 | new |
| | 22 | To know that ANVISA (Agência Nacional de Vigilância Sanitária) is responsible for the approval of medical devices in Brazil. | *ANVISA is an authority, to which the manufacturer submits the documents for the approval.* | - | C1 | new |
| | 23 | To know that the NMPA (National Medical Products Administration) is responsible for the approval of medical devices in China. | *NMPA is an authority, to which the manufacturer submits the documents for the approval.* | - | C1 | new |
| | 24 | To know that the PMDA (Pharmaceutical and Medical Devices Agency) is responsible | *PMDA is an authority, to which the manufacturer submits the documents for the approval.* | - | C1 | new |

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| | | for the approval of medical devices in Japan. | | | | |
| | 25 | To know that the ... is responsible for the approval of medical devices in Russia. | *... is an authority, to which the manufacturer submits the documents for the approval.* | - | C1 | new |
| | 26 | To know that the TGA (Therapeutic Goods Administration) is responsible for the approval of medical devices in Australia. | *TGA is an authority, to which the manufacturer submits the documents for the approval.* | - | C1 | new |

## 2. Risk management curriculum

| chapter | ID | Learning objective | *explanation* | FL | AL | Reference to Curriculum 2.0 |
|---|---|---|---|---|---|---|
| **2** | | **Risk management** | | | | |
| **2.1** | | **Introduction to risk management** | | | | |
| **2.1.1** | | **Regulatory requirements** | | | | |
| | 1 | To know that the MDR requires a risk management system. | *RM system must satisfy Annex I Section 3; manufacturers must create, document, and maintain.* | C1 | - | M2-LE1.1-1-1. |
| | 2 | To know the MDR requirements that apply to risk management. | *Show MDR articles, refer to ISO 13485* | C1 | - | M2-LE4.1-1-1. |
| | | - | | | | M2-LE1.1-1-1 |
| | 3 | To know that EN ISO 14971 is suitable as a harmonized standard to satisfy the MDR requirements that apply to risk management systems. | *Demonstrate connection between principle of presumption and the essential safety and performance requirements.* | C1 | - | M2-LE1.1-1-1 |
| | | | *Too vague* | | | M2-LE1.1-1-1 |
| | 4 | To understand why EN ISO 14971 is suitable as a harmonized standard to satisfy the MDR requirements that apply to risk management systems. | *Demonstrate coverage between standard and MDR requirements.* | - | C2 | new |
| | 5 | To know that various standards normatively require the application of ISO 14971. | *Merely name the standards, but do not explain IEC 62304, IEC 60601-1, IEC 62336.* | C1 | - | M2-LE1.1-1-1 |
| | 7 | To be able to allocate the developer activities prescribed by EN 62304 to the risk activities prescribed by EN ISO 14971 (and vice versa). | *Formulate comparison.* | - | C2 | M2-LE1.1-1-1 |
| | | - | | | | M2-LE1.1-1-1. |
| | 8 | To know that risk management refers to both the safety and performance aspects. | *Medical devices may cause harm in two ways, demonstrate difference.* | C1 | - | new |

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| | 9 | To know the definition of the term "performance." | *See MDR and various device standards.* | C1 | - | new |
| | 10 | To know the definition of the term "safety." | *See device standards.* | C1 | - | new |
| **2.1.2** | | **Definitions of terms** | | | | |
| | 11 | To know the definitions of the terms "hazard," "hazardous situation," "harm." | | C1 | - | M2-LE1.2-1-1 |
| | 12 | To know the definition of the terms "risk" and "benefit." | *See EN ISO:2019.* | C1 | - | new |
| | 13 | To be able to distinguish between the terms "hazard" and "hazardous situation." | *Formulate examples.* | C2 | - | M2-LE1.2-1-1 |
| | 14 | To be able to name examples of hazards in relation to standalone software. | *Delineation of physical hazards (in the case of devices) and hazards in relation to standalone SW.* | - | C2 | new |
| **2.1.3** | | **Risk management planning** | | | | |
| | 15 | To know that risk management must be planned and documented for each product. | | C1 | - | M2-LE4.3-1-1 |
| | 16 | To know the most important planning contents. | *Display ISO flowchart.* | C1 | - | M2-LE4.3-1-1 |
| **2.1.4** | | **Risk management file** | | | | Inhalt der Risikomanagementakte |
| | 17 | To know the typical structure of a risk management file. | *Display overview.* | C1 | - | M2-LE5.1-1-1 |
| | 18 | To know that conformity is verified by inspection of the file. | | - | C1 | M2-LE5.1-1-1 |
| | | - | | | | M2-LE5.1-1-1. |
| **2.2** | | **The risk management process according to ISO 14971** | | | | |
| **2.2.1** | | **General requirements** | | | | |
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| | 1 | To know that the responsibility for risk management rests with senior management. | *Also a requirement together with ISO 13485* | C1 | - | |
| | 2 | To know that senior management must also define the policy for determining acceptable risk. | | C1 | - | |
| **2.2.2** | | **The risk management process** | | | | |
| | | - | | | | M2-LE4.2-1-1 |
| | 3 | To know that the risk management process is applicable to the entire product life cycle, including disposal. | *Disposal applies also to standalone SW.* | C1 | - | M2-LE4.2-1-2 |
| | 4 | To know the sequence of the activities in the risk management process. | *Go through flowchart from the standard.* | C1 | - | M2-LE4.2-1-3 |
| | | - | | | | M2-LE4.2-1-4 |
| **2.2.3** | | **Intended purpose and intended use** | | | | |
| | | - | | | | M2-LE4.4-1-1 |
| | 5 | To know that the intended purpose must be created and documented. | *Display the EN ISO definition.* | C1 | - | |
| | 6 | To know that the intended purpose must also describe reasonably foreseeable misuse. | *Briefly explain term.* | - | C1 | M2-LE4.4-1-1 |
| | 7 | To know that product characteristics with a safety aspect must be described. | *See questions in Annex C to EN ISO.* | - | C1 | M2-LE4.4-1-1 |
| | 8 | To know the definition of the term "intended purpose." | *Briefly display content also.* | - | C1 | |
| | 9 | To know that the risk analysis includes the intended use. | | - | C1 | new |
| **2.2.4** | | **Hazard and risk analysis** | | | | Identifizierung von Gefährdungen und Einschätzen der Risiken |
| | 10 | To know that a risk is assessed by estimating the severity and likelihood of harm. | *Build bridge to acceptance matrix.* | C1 | - | M2-LE4.5-1-1 |

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| | | - | | | | M2-LE4.5-1-1 |
| | | - | | | | M2-LE4.5-1-1 |
| **2.2.5** | | **Risk assessment matrix** | | | | Risikoakzeptanz |
| 2.2.5.1 | | Structure and purpose of the matrix | | | | |
| | 11 | To know a possibility for the display of the risk matrix. | *Display* | C1 | - | M2-LE2.1-1-1 D |
| | 12 | To know that the frequency distribution of risks can be displayed in the risk matrix. | *Distribution of all risks to the classes.* | C1 | - | M2-LE2.1-1-1 |
| | | - | | | | M2-LE2.1-1-1 |
| | 13 | To know that the risk assessment matrix is product- and company-specific. | | C1 | - | M2-LE2.1-1-1 |
| | 14 | To know that the risk assessment matrix expresses the manufacturer's risk policy. | | C1 | - | M2-LE2.1-1-1 |
| 2.2.5.2 | | The probability axis | | | | Die Achsen der Risikomatrix |
| | 15 | To know the factors for the value ranges of the probability axis. | *Qualitative, quantitative number of uses, duration of use, etc.* | C1 | - | M2-LE2.2-1-1 |
| | 16 | To know that the likelihood of harm is being evaluated. | *Differentiate between likelihood, fault, and harm.* | C1 | - | M2-LE2.2-1-1 |
| 2.2.5.3 | | The severity axis | | | | |
| | 17 | To know that harm is expressed in different degrees of severity. | *Demonstrate that there are quantitative approaches, such as degree of impairment, expected reduction in lifetime.* | C1 | - | M2-LE2.2-2-1 |
| | 19 | To be able to review formulations of degrees of severity for accuracy. | *Provide and have participants formulate case example.* | - | C2 | new |
| **2.2.6** | | **Risk evaluation and risk acceptance** | | | | |
| | 20 | To know that the standard provides no specifications for the acceptability of risks. | *Product- and company-specific* | C1 | - | M2-LE2.3-1-1 |

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| | 21 | To know that risks per se are not permitted to be accepted. | *See ZA:2012; manufacturer must quantify benefits; see also clinical evaluation.* | C1 | - | new |
| | 22 | To know that the criteria for the acceptability of risks must be guided by the state of the art. | | C1 | - | M2-LE2.3-1-1. |
| **2.2.7** | | **Risk control** | | | | |
| | 23 | To know the sequence in which attempts must be made to control identified risks. | *MDR, analysis of options for selection* | C1 | - | M2-LE4.6-1-1 |
| | 24 | To know that measures must reflect the state of the art. | *Explain the significance of type standards.* | C1 | - | M2-LE4.6-1-1. |
| | 25 | To understand the impact of options for selection on an individual risk. | *Reduce severity, harm, or eliminate risk.* | C1 | - | M2-LE4.6-1-1 |
| | 26 | To know that new risks may result from risk control measures. | *Show examples.* | C1 | - | M2-LE4.6-1-1 |
| | 27 | To know that the implementation and also the efficacy of the measures must be verified. | *Explain what efficacy means.* | C1 | - | M2-LE4.6-1-1. |
| | 28 | To know that IEC 60601-1 itself is already a risk analysis with measures and the manufacturer must especially analyze risks in relation to functionality. | *Display standard and also explain 24971 that describes the correlation in the AL.* | - | C1 | new |
| **2.2.8** | | **Risk/benefit assessment** | | | | Restrisiko und Risiko-Nutzen-Analyse |
| | 29 | To know that when residual risks are not acceptable, the product can still be placed on the market when the benefits outweigh the risks. | *Collect literature and data as evidence.* | C1 | - | M2-LE4.7-1-1 |
| | 30 | To know that multiple measures may be necessary until the residual risk is acceptable. | *Explain iterative process for risk control.* | C1 | - | M2-LE4.7-1-1 |
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| **2.2.9** | | **Overall residual risk and risk management report** | | | | new |
| | 31 | To know that significant residual risks must be disclosed. | | - | C1 | new |
| | 32 | To know that overall residual risk is evaluated on the basis of the risk matrix. | *Show difference between individual risk and overall residual risk.* | - | C1 | new |
| | 33 | To understand the difference between individual risk and overall residual risk. | | - | C2 | new |
| | 34 | To know that a risk management report must be created. | | C1 | - | new |
| | 35 | To know the contents of a risk management report. | | - | C1 | new |
| | 36 | To know that the risk management report evaluates the plan and the analysis, but not the product. | | C1 | - | new |
| **2.2.10** | | **Post-production phase** | | | | |
| | 37 | To know that manufacturers must verify the validity of the assumptions throughout the entire product life cycle. | | - | C1 | M2-LE4.8-1-1 |
| | 38 | To know that manufacturers must systematically collect information on the product during the marketing phase. | *Briefly mention PMS and justify benefits.* | - | C1 | M2-LE4.8-1-1 |
| | 39 | To know the most important information sources. | *BfArM, Swissmedic, FDA, etc.* | - | C1 | M2-LE4.8-1-1 |
| | 40 | To know that the state of the art must also be tracked during the marketing phase. | *Explain that this applies especially to standards.* | - | C1 | M2-LE4.8-1-1 |
| | 41 | To know that the manufacturer must continue to monitor product risks following placement on the market. | *Display standard requirements that apply to market surveillance, clinical evaluation and clinical follow-up* | - | C1 | new |

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| | 42 | To know the potential information sources for market surveillance. | *Public notices, information on the state of the art, information on installation, application, and maintenance* | - | C1 | new |
| | 43 | To know that the risks associated with IT security must be analyzed and evaluated. | *To be merely mentioned, no concrete specifications in the standard and MDR.* | C1 | - | new |
| | | - | | | | M2-LE1.2-1-1 |
| | | - | | | | M2-LE2.2-1-1 |
| | 44 | To be able to create a probability axis on the basis of an example. | *Provide and have participants formulate case example.* | - | C2 | M2-LE2.2-1-1 |
| **2.3** | | **Risk analysis procedure** | *Change title.* | | | Verfahren/Techniken der Risikanalyse |
| **2.3.1** | | **Fundamentals of risk analysis** | | | | |
| | 1 | To know what the objective of hazard analysis is. | | C1 | - | M2-LE3.1-1-1 |
| | 2 | To know that the identification of hazards is a sub-task of risk analysis. | *Display flowchart of the risk process.* | C1 | - | M2-LE3.1-1-1 |
| | 3 | To know that the standard provides no specifications for the techniques. | *Display list of potential techniques.* | C1 | - | M2-LE3.1-1-1 |
| **2.3.2** | | **Preliminary Hazard Analysis** | | | | Vorläufige Gefährdungsanalyse (Preliminary Hazard Analysis, PHA) |
| | 4 | To know that the PHA uses checklists to identify hazards. | | C1 | - | M2-LE3.2-1-1 |
| | 5 | To know the two checklists in the annex to ISO 14971. | *Annex C and Table E.1* | C1 | - | M2-LE3.2-1-1 |
| | 6 | To understand how the PHA can be used in relation to the intended purpose. | *Analyze performance features.* | - | C2 | M2-LE3.2-1-1 |
| | 7 | To formulate a PHA for a case example of a standalone SW. | *Work through case example using the checklists.* | - | C3 | M2-LE3.2-1-1 |
| **2.3.3** | | **Fault Tree Analysis** | | | | |

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| . | 8 | To know that the FTA is suitable for identifying the root causes of hazards. | *Continuation of the PHA* | C1 | - | |
| | 9 | To know that the FTA is a top-down analysis. | *Display tree diagram, top incident with root cause* | - | C1 | M2-LE3.3-1-1 |
| | 10 | To know that the architecture must be largely known. | *If there is not yet any system architecture, then use functional architecture.* | - | C1 | M2-LE3.3-1-1 |
| | 11 | To understand how the FTA can be quantitatively used. | *Combination of probabilities* | - | C2 | M2-LE3.3-1-1 |
| | 12 | To understand how the FTA can be qualitatively used. | *Evaluation of first failure safety and defects with common failure cause* | - | C2 | M2-LE3.3-1-1 |
| **2.3.4** | | **Failure Mode and Effects Analysis (FMEA)** | | | | |
| | | - | | | | M2-LE3.4-1-1 |
| | 13 | To know that the FMEA considers the cause-and-effect relationship. | *Explain bottom-up.* | C1 | - | M2-LE3.4-1-2 |
| | 14 | To know that the FMEA is suitable for identifying new hazards. | *New hazards are identified on the basis of the technical solution and design defects.* | C1 | - | M2-LE3.4-1-3. |
| | | - | | | | M2-LE3.4-1-1 |
| **2.4** | | **Documentation** | | | | Risikomanagementakte |
| | 1 | To know the recommended structure of a risk table. | *Display and go over example* | - | C1 | M2-LE5.2-1-1 |
| | 2 | To be able to review a risk table for accuracy and completeness. | *Demonstrate using case example with errors.* | - | C2 | newn |
| **2.5** | | **Risk management for software** | | | | |
| | 1 | To understand that the SW itself does not constitute a hazard, but rather that it influences hazardous situations. | *Show difference between embedded SW and standalone SW.* | C2 | - | M2-LE6.2-1-1 |
| | | - | | | | M2-LE6.2-1-1 |
| | | - | | | | M2-LE6.2-2-1 |
| | 2 | To know what typical design and development errors are. | *Display list from standard.* | - | C1 | M2-LE6.2-2-1. |
| | 3 | To know that software errors are systematic errors that can only be | *Explain difference between systematic and random errors.* | - | C1 | M2-LE6.2-2-1 |

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| | | effectively avoided by controlling the design process. | | | | |
| | 4 | To know that probabilities should not be expected for risks caused by SW. | *See recommendation from 80002-1.* | - | C1 | M2-LE6.2-3-1 |
| | | - | | | | M2-LE6.2-3-1 |
| | | - | | | | M2-LE6.2-4-1 |
| | 5 | To be able to create an FMEA for SW based on an example. | *Provide case example and have participants create their own.* | - | C3 | M2-LE6.2-4-1 |
| | 6 | To be able to create an FTA for SW based on an example. | *Provide case example and have participants create their own.* | - | C3 | |
| **2.6** | | **IEC 80002-1** | | | | Zusammenspiel der ISO 14971 mit anderen Normen |
| | 1 | To know that the IEC 80002 standard is a supplementary standard with the nature of a guideline to supplement the ISO 14971 standard. | | C1 | - | M2-LE6.3-1-1 |
| | 2 | To understand that the IEC 80002 standard closes a gap in the field of software safety. | | - | C1 | M2-LE6.3-1-1 |
| | 3 | To know that for each process step in the ISO 14971 standard, there is a software-specific counterpart in the IEC 80002 standard. | | - | C1 | M2-LE6.3-1-1 |
| | 4 | To know that the IEC 80002 standard provides application information for all fields of biomedical engineering software which are not already covered by existing standards. | | - | C1 | M2-LE6.3-1-1 |

## 3. Software engineering curriculum

| chapter | ID | Learning objective | *explanation* | FL | AL | Reference to Curriculum 2.0 |
|---|---|---|---|---|---|---|
| **3** | | **Software engineering** | | | | |
| **3.1** | | **Software development processes** | | | | |
| **3.1.1** | | **Regulatory requirements** | | | | |
| | 1 | To know that the IEC 62304 standard requires a description of the software development process. | | C1 | - | M3-LE1.1-1-1 |
| | 2 | To know that the software development process must be based on the harmonized standards in order to justify the conformity assumption. | | C1 | - | M3-LE1.1-1-1 |
| **3.1.2.** | | **Process models** | | | | |
| | 9 | To know that the IEC 62304 standard does not prescribe any particular process model. | *In other words, the waterfall model and the V-model can be applied, just as iterative incremental models and agile models can.* | C1 | - | M3-LE1.2-1-1 |
| | 10 | To know that agile software development can be reconciled with the requirements of the IEC 62304 standard. | | C1 | - | |
| | 11 | To be able to understand and assess advantages and drawbacks of agile development models for the development of software as a medical device. | | - | C3 | M3-LE1.2-1-1 |
| **3.1.3** | | **Process description** | | | | |
| | 12 | To know which processes must be defined in advance. | | C1 | - | M3-LE1.3-1-1 |

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| | 13 | To know which processes must be implemented if the software is an independent medical device. | | C1 | - | M3-LE1.3-1-1 |
| | 14 | To know necessary measures for maintenance and traceability of process descriptions. | | - | C2 | M3-LE1.3-1-1 |
| **3.2** | | **Development planning** | | | | |
| | 1 | To know the required contents of a software development plan. | | C1 | - | M3-LE2.1-1-1 |
| | 2 | To know that a specification of the standards, methods, and tools to be used is prescribed for safety class C software. | | C1 | - | M3-LE2.1-1-1 |
| **3.3** | | **Software requirements analysis** | | | | |
| **3.3.1** | | **Identifying requirements** | | | | |
| | 1 | To understand that the IEC 62304 standard assumes that the software requirements are derived from system requirements. | | C2 | - | M3-LE3.1-1-1 |
| | 2 | To know the special significance of risk control measures in the software requirements. | | C1 | - | M3-LE3.1-1-1 |
| **3.3.2** | | **Documenting requirements** | | | | |
| | 3 | To understand the importance of the documentation of requirements. | | C2 | - | M3-LE3.2-1-1 |
| | 4 | To understand why a renewed evaluation of the risk analysis is necessary following changes or | | C2 | - | M3-LE3.2-1-1 |

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| | | supplements to the requirements. | | | | |
| **3.3.3** | | **Verifying requirements** | | | | |
| | 5 | To know the requirements of the IEC 62304 standard that apply to the verification of software requirements. | | C1 | - | M3-LE3.3-1-1 |
| | 6 | To understand the significance of the essential quality criteria of software requirements in relation to the IEC 62304 standard. | | C2 | - | M3-LE3.3-1-1. |
| **3.3.4** | | **Managing requirements** | | | | |
| | 7 | To understand that requirement management tools facilitate the fulfillment of certain requirements of the IEC 62304 standard. | | - | C2 | M3.4-1-1 |
| **3.4** | | **Software architecture** | | | | |
| **3.4.1** | | **Describing software architecture** | | | | |
| | 1 | To be able to explain the subdivision of the software into software components and software units. | | C2 | - | M3-LE4.1-1-1 |
| | 2 | To know that the IEC 62304 standard requires only the description of the static architecture view. | | C1 | - | M3-LE4.1-1-1 |
| | 3 | To know what a dynamic view describes. | | - | C1 | M3-LE4.1-2-1 |
| **3.4.2** | | **Safety categories** | | | | |
| | 4 | To know the definition of the term "software safety category." | | C1 | - | new |
| | 5 | To know the criteria for the three | *Provide evaluation criteria.* | C1 | - | M2-LE6.1-1-1 |

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| | | software safety categories (A, B, and C). | | | | |
| | 6 | To know that the SW safety category controls the scope of the development activities and thus also the scope of the documentation. | *Display flowchart from IEC 62304 and allocate activities.* | C1 | - | M2-LE6.1-1-1 |
| | 7 | To know that the SW safety category is able to be defined separately for independent software systems and sub-systems. | *Display possibilities of reduction.* | C1 | - | new |
| | 8 | To know how to proceed when reducing the safety categories. | | C1 | - | M3-LE4.2-2-1 |
| | 9 | To understand how the definition of the SW safety category relates to the assessment of existing measures. | *Display and go over flowchart from IEC 62304.* | C2 | - | M2-LE6.1-1-1 |
| | 10 | To know that the definition of the SW safety category is not the risk analysis. | | C1 | - | M2-LE6.1-1-1 |
| | 11 | To be able to determine the software safety category. | *A, B, C; see standard.* | - | C2 | M3-LE4.2-1-1 |
| | 12 | To understand how individual software components are able to be classified differently. | | - | C2 | M3-LE4.2-1-1 |
| | 13 | To know that the classification into safety categories is practically identical with the FDA Level of Concern, but entails different consequences. | | - | C1 | M3-LE4.2-2-1 |
| **3.4.3** | | **Ensuring risk treatment** | | | | |
| | 14 | To understand how software components of different software | | C2 | - | M3-LE4.3-1-1 |

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| | | safety categories are able to be differentiated from one another. | | | | |
| **3.4.4** | | **Verifying software architecture** | | | | |
| | 15 | To know the issues on which the verification of the software architecture will focus. | | C1 | - | M3-LE4.4-1-1 |
| **3.5** | | **SW design** | | | | |
| **3.5.1** | | **Describing software design** | | | | |
| | 1 | To be able to name suitable means of representation for the description of the static view and of time-critical processes. | | - | C1 | M3-LE5.1-1-1 |
| | 2 | To know when a description of the software design is required. | | C1 | - | M3-LE5.1-1-1 |
| **3.5.2** | | **Defining interfaces** | | | | |
| | 3 | To be able to name possible forms of documentation for interfaces between software components. | | C1 | - | M3-LE5.2-1-1 |
| | 4 | To know that at the software design level, a detailed interface description is prescribed only for category C components, whereas at the architecture level, this is required for categories B and C. | | C1 | - | M3-LE5.2-1-1 |
| **3.5.3** | | **Verifying design** | | | | |
| | 5 | To know that the software design for software safety category C components must be verified. | | C1 | - | M3-LE5.3-1-1 |

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| | 6 | To know that proof of proper implementation of the software architecture must be provided for software safety category C components. | | C1 | - | M3-LE5.3-1-1 |
| **3.6** | | **SW implementation** | | | | |
| **3.6.1** | | **Implementing software units** | | | | |
| | 1 | To know that the IEC 62304 standard does not include any specifications regarding the technology or method of implementation. | | C1 | - | M3-LE6.1-1-1 |
| **3.6.2** | | **Defining acceptance criteria** | | | | |
| | 2 | To know that acceptance criteria must be defined for software safety category B and C software units. | | C1 | - | M3-LE6.2-1-1 |
| | 3 | To know that it must be ensured that a software unit satisfies the acceptance criteria prior to integration of such software units. | | C1 | - | M3-LE6.2-1-1 |
| | 4 | To know that the IEC 62304 standard requires explicit acceptance criteria for safety category C software units. | | C1 | - | M3-LE6.2-1-1 |
| | 5 | To know that excessively rigorous acceptance criteria can be a potential source of high costs. | | - | C1 | M3-LE6.2-1-1 |
| | 6 | To know the acceptance criteria for category C software units required by the IEC 62304 standard. | | C1 | - | M3-LE6.2-1-1 |
| **3.6.3** | | **Using coding guidelines** | | | | |

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| | 7 | To know typical components of coding guidelines. | | C1 | - | M3-LE6.3-1-1 |
| | 8 | To know what has to be taken into account when using coding guidelines as an acceptance criterion. | | C1 | - | M3-LE6.3-1-1 |
| **3.6.4** | | **Verifying software units** | | | | |
| | 9 | To know the requirements of the IEC 62304 standard and FDA that apply to the verification of software units. | | C1 | - | M3-LE6.4-1-1 |
| | 10 | To know the common methods for verifying the acceptance criteria. | *Static code analysis, code review, unit test* | C1 | - | M3-LE6.4-1-1 |
| | 11 | To be able to assess which form of verification is suitable for which acceptance criteria. | | - | C3 | M3-LE6.4-1-1 |
| **3.7** | | **Software integration** | | | | |
| | 1 | To know the contents of the software integration plan. | | C1 | - | M3-LE7.1-1-1 |
| | 2 | To know the steps for the verification of software integration. | | C1 | - | M3-LE7.1-1-1 |
| | 3 | To know the different strategies for software integration. | *Top-down, bottom-up, Big Bang, continuous integration* | - | C1 | M3-LE7.1-1-1 |
| | 4 | To be able to evaluate the different strategies for software integration. | | - | C2 | M3-LE7.1-1-1 |
| **3.8** | | **Software test** | | | | |
| **3.8.1** | | **General requirements from the IEC 62304 standard** | | | | |
| | 1 | To know which tests must be performed based on the software safety category. | | C1 | - | M3-LE8.1-1-1 |
| | 2 | To know the objective and | | C1 | - | M3-LE8.1-1-1 |

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| | | contents of SW integration testing. | | | | |
| | 3 | To know the objective and contents of the SW system test. | | C1 | - | M3-LE8.1-1-1 |
| | 4 | To know the main components of test planning and their focus. | | - | C1 | M3-LE8.1-2-1 |
| | 5 | To know what must be specified in detail in connection with the test cases. | | - | C1 | M3-LE8.1-2-1 |
| | 6 | To know that it is permitted to combine integration testing and SW system testing. | | C1 | - | M3-LE8.1-2-1 |
| | 7 | To know the required documentation of test implementation. | | C1 | - | M3-LE8.1-3-1 |
| | 8 | To know how to deal with the faults found in the test. | | C1 | - | M3-LE8.1-3-1 |
| | 9 | To know which tests must be carried out after changes. | | C1 | - | M3-LE8.1-4-1 |
| | 10 | To know the criteria for verification of the software system test according to the IEC 62304 standard. | | C1 | - | M3-LE8.2-1-1. |
| **3.8.2** | | **Verification vs. validation** | | | | |
| | 11 | To know the difference between validation and verification. | | C1 | - | M3-LE8.2-2-1 |
| | 12 | To know common validation methods. | | - | C1 | M3-LE8.2-2-1 |
| **3.9** | | **Software release** | | | | |
| | 1 | To know the prerequisites for a software release. | | C1 | - | M3-LE9.1-1-1 |
| | 2 | To know the archiving period for software. | *The longer of the following two periods: life cycle of the MEDICAL DEVICE SOFTWARE, as defined by the MANUFACTURER, or* | C1 | - | M3-LE9.1-1-1 |

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| | | | *the time span defined based on the relevant, regulatory requirements* | | | |
| | 3 | To understand why the reliable delivery of the software must be ensured. | | C2 | - | M3-LE9.1-1-1 |
| **3.10** | | **Software configuration management** | | | | |
| **3.10.1** | | **Configuration items** | | | | |
| | 1 | To know the various items that have to be checked using configuration management. | | C1 | - | M3-LE10.1-1-1 |
| **3.10.2** | | **Necessity of configuration management** | | | | |
| | 2 | To understand when and why configuration items must be checked. | | C2 | - | M3-LE10.2-1-1 |
| **3.10.3** | | **Identifying configuration items** | | | | |
| | 3 | To know a typical scheme for identification of configuration items. | | C1 | - | M3-LE10.3-1-1. |
| | 4 | To understand which attributes are suitable for the clear identification of configuration items. | | C2 | - | M3-LE10.3-1-2 |
| **3.10.4** | | **Tools for configuration management** | | | | |
| | 5 | To know tools for configuration management and their fields of application. | | - | C1 | M3-LE10.4-1-1 |
| **3.10.5** | | **Configuration management plan** | | | | |
| | 6 | To know the contents of a configuration management plan. | | C1 | - | M3-LE10.5-1-1 |
| **3.10.6** | | **Change management** | | | | |
| | 7 | To understand the necessity of change management. | | C2 | - | M3-LE10.6-1-1 Die Notwendigkeit des Änderungsmanagements verstehen. |

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| | 8 | To know the fundamental requirements from the IEC 62304 standard that apply to change management. | | C1 | - | M3-LE10.6-1-1 |
| **3.11** | | **Software maintenance** | | | | |
| **3.11.1** | | **Planning of software maintenance** | | | | |
| | 1 | To know sources for feedback concerning medical device software. | | C1 | - | M3-LE11.1-1-1 |
| | 2 | To know the criteria for reaching a decision as to whether feedback represents a problem. | | C1 | - | M3-LE11.1-1-2 |
| | 3 | To know that the risk management process must be incorporated into the surveillance of feedback. | | C1 | - | M3-LE11.1-1-3 |
| | 4 | To know the requirements that apply to the surveillance of SOUP components. | | C1 | - | M3-LE11.1-1-4 |
| **3.11.2** | | **Analysis of problems and changes** | | | | |
| | 5 | To be able to name examples of the surveillance of feedback. | *Hotline, BfArM reports, Internet forums, internal departments, etc.* | C1 | - | M3-LE11.2-1-1 |
| | 6 | To understand the difference between feedback and problem. | | C2 | - | M3-LE11.2-1-2 |
| | 7 | To know that the problem-solving process must be incorporated. | | C1 | - | M3-LE11.2-1-3 |
| | 8 | To know that change requests must be analyzed and approved. | | C1 | - | M3-LE11.2-1-4 |
| | 9 | To know which information must be forwarded to users | | - | C1 | M3-LE11.2-1-5 |

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| | | and competent authorities. | | | | |
| **3.11.3** | | **Implementation of changes** | | | | |
| | 10 | To know that the activities necessary for the change must be identified and implemented. | | C1 | - | M3-LE11.3-1-1. |
| | 11 | To know that the software must be re-approved following the change. | | C1 | - | M3-LE11.3-2-1 |
| | 12 | To be able to provide examples for the delivery of changed software. | *Complete software system, "change kit," update, upgrade, patch, etc.* | C1 | - | M3-LE11.3-2-1. |
| **3.12** | | **Software problem-solving** | | | | |
| | 13 | To know the required contents of problem reports. | *Statement concerning criticality, helpful information for problem-solving* | C1 | - | M3-LE12.1-1-1 |
| | 14 | To know that a change request can result from an investigation of a problem. | | C1 | - | M3-LE12.1-1-1 |
| | 15 | To know that all problems must be investigated for their relevance to safety. | | C1 | - | M3-LE12.1-2-1 |
| | 16 | To know that it may be necessary to notify involved parties concerning the problem. | *Examples include users, authorities.* | C1 | - | M3-LE12.1-3-1 |
| | 17 | To know that change requests must be implemented using the change control process. | | C1 | - | M3-LE12.1-2-1 |
| | 18 | To know that problem reports must be analyzed for trends. | | C1 | - | M3-LE12.1-4-1 |
| **3.13** | | **Traceability in the SW development process** | | | | |
| **3.13.1** | | **Fundamentals** | | | | |

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| | 1 | To know the requirements of the IEC 62304 standard with regard to traceability. | *Point out that the topic comes up at different points in the standard: 5.7.4; 7.3.3; 8.2.4.* | C1 | - | M3-LE13.1-1-1 |
| | 2 | To know the requirements of FDA Guidance "General Principles of Software Validation" with regard to traceability. | | C1 | - | M3-LE13.1-1-1 |
| | 3 | To know the special significance of the traceability of risk control measures. | | - | C1 | M3-LE13.1-1-1 |
| **3.13.2** | | **Tracing** | | | | |
| | 4 | To understand the purpose and structure of a trace matrix. | | - | C2 | M3-LE13.2-1-1 |
| | 5 | To be able to create a trace matrix. | | - | C3 | M3-LE13.2-1-1 |
| | 6 | To understand that tracing with current tools can be performed with significantly less effort than manually. | | - | C2 | M3-LE13.2-1-1 |
| **3.14** | | **Software of Unknown Provenance (SOUP)** | | | | |
| **3.14.1** | | **Definition and examples of SOUP** | | | | |
| | 1 | To know the definition of "SOUP." | | C1 | - | M3-LE14.1-1-1 |
| | 2 | To understand the advantages and drawbacks of using SOUP. | | C2 | - | M3-LE14.1-1-1 |
| | 3 | To know that the manufacturer is also liable for damages attributable to a fault in the SOUP. | | C1 | - | new |
| **3.14.2** | | **Handling software of unknown provenance** | | | | |
| | 4 | To know how SOUP must be identified in configuration management | | C1 | - | M3-LE14.2-1-1 |

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| | | according to the IEC 62304 standard. | | | | |
| | 5 | To know that SOUP must be taken into account particularly in risk management. | | C1 | - | M3-LE14.2-1-1 |
| | 6 | To know that SOUP must be taken into account in the SW maintenance process. | | C1 | - | M3-LE14.2-1-1 |
| | 7 | To know that there are additional requirements that apply to SOUP in connection with safety category B and C software. | *Specification of functional and performance requirements*<br>*Specification of the system hardware and software required for SOUP components* | C1 | - | M3-LE14.2-1-1 |
| | 8 | To know that known anomalies associated with SOUP must be evaluated. | | C1 | - | new |
| | 9 | To understand why a precise segregation of the use of SOUP helps to meet the normative requirements. | | - | C2 | M3-LE14.2-1-1 |
| | 10 | To know that the documentation for OTS software to be submitted to the FDA depends on the software's possible impact on the safety of patients, users and third parties. | | - | C1 | M3-LE14.2-2-1 |
| | 11 | To know the span between the minimum documentation to be generated and the maximum requirements of the FDA (depending on the classification). | | - | C1 | M3-LE14.2-2-1 |
| | 12 | To understand how the FDA classifies OTS software according to its hazard potential. | | - | C2 | M3-LE14.2-2-1 |

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| | 13 | To know common features and differences of the requirements of the FDA and IEC 62304 with regard to SOUP. | | - | C1 | M3-LE14.2-2-1 |
| **3.15** | | **Tool validation** | | | | |
| **3.15.1** | | **Introduction** | | | | |
| | 1 | To know the delineation between software tools and SOUP. | | - | C1 | M3-LE15.1-1-1 |
| | 2 | To understand the necessity of tool validation. | | - | C2 | M3-LE15.1-2-1 |
| | 3 | To be able to name the standards relevant for tool validation. | | - | C1 | aM3-LE15.1-2-1 |
| | 4 | To know the requirements of the relevant standards with regard to tool validation. | | - | C1 | M3-LE15.1-2-1 |
| **3.15.2** | | **Tool validation in practice** | | | | |
| | 5 | To know the significance of the validation plan. | | - | C1 | M3-LE15.2-1-1 |
| | 6 | To know the contents of a validation plan. | | - | C1 | M3-LE15.2-1-1 |
| | 7 | To understand how the purpose of use as well as requirements to be met by the tool determine the validation plan. | | - | C2 | M3-LE15.2-3-1 |
| | 8 | To understand that risks can arise through the use of tools. | | - | C2 | M3-LE15.2-5-1 |
| | 9 | To know procedures by means of which the impact of malfunctions of a tool on the device to be produced can be limited. | | - | C1 | M3-LE15.2-5-1 |
| | 10 | To understand that the tests of the requirements that apply to tools must | | - | C2 | M3-LE15.2-6-1 |

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| | | be planned and specified. | | | | |
| | 11 | To understand what must be considered in the implementation of the tests. | | - | C2 | M3-LE15.2-6-1 |
| | 12 | To know the artifacts to be archived at the end of a tool validation. | | - | C1 | M3-LE15.2-7-1. |
| **3.15.3** | | **Maintenance of the tools** | | | | |
| | 13 | To understand why tools have to undergo maintenance and that a revalidation is then required. | | - | C2 | M3-LE15.3-1-1 |
| | 14 | To know that known faults of the tool must be monitored regularly and must, if necessary, be taken into account in the validation. | | - | C1 | M3-LE15.3-1-1 |

## 4. Usability curriculum

| chapter | ID | Learning objective | Explanation | FL | AL | Reference to curriculum 2.0 |
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| **4** | | **Usability** | | | | |
| **4.1** | | **Usability fundamentals** | | | | |
| **4.1.1** | | **General requirements** | | | | |
| | | - | | | | M4-LE1.1-1-1 |
| | | - | | | | M4-LE1.1-1-1 |
| | 1 | To understand why a usability-oriented development process is important and provides advantages. | ** Comply with laws*<br>** Increase product safety*<br>** Increase market success*<br>** Reduce development costs* | C2 | - | M4-LE1.1-2-1 |
| | | - | | | | M4-LE1.1-3-1 |
| | 2 | To understand that usability can only be determined in a defined context of use. | *Different use contexts nearly always lead to different use requirements (such as operating room vs. ambulance vs. home use).* | C2 | - | M4-LE1.1-4-1 |
| | | - | | | | M4-LE1.1-4-1 |
| | 3 | To know that there is a supplementary technical report in conjunction with IEC 62366-1 (IEC/TR 62366-2) that explains the application of 62366-1. | *The tasks of the CPMS include providing additional information.* | C1 | - | |
| **4.1.2** | | **Terminology in the context of usability** | | | | |
| | 4 | To understand the relationship between "intended use," "proper use," "use error," and "abnormal use." | *See 62366-1, Figure 1.* | - | C2 | M4-LE1.1-5-1 |
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| | | - | | | | M4-LE1.2-1-1 |
| | 5 | To understand the difference between usability, ergonomics, utility, and user experience. | ** Usability (IEC 62366-1, 3.16)*<br>** Ergonomics (not defined; among objectives of usability, software ergonomics: The SW enables cognitive and physical adaptation)*<br>** Utility (not defined; among objectives of usability: A device should maintain its safe, operable condition)*<br>** User experience (not defined; usability is part of the user experience, but usability only considers the measurable part of the user experience)* | - | C2 | M4-LE1.2-1-1 |
| | 6 | To know the definition of usability. | *Definition per IEC 62366-1* | C1 | - | M4-LE1.2-2-1 |
| | 7 | To know the definition of formative and summative evaluation. | *Definition per IEC 62366-1* | C1 | - | M4-LE1.2-2-1 |
| **4.2** | | **Regulatory requirements** | | | | |
| **4.2.1** | | **Regulatory requirements (Europe)** | | | | |
| | 1 | The know the relationships between IEC 62366-1 and other standards. | ** 62366-1 compulsorily requires ISO 14971*<br>** 60601-1-6 refers to 62366-1* | C1 | - | M4-LE2.1-1-1 |
| | 2 | To know the contents of the essential safety and performance requirements per the MDR that require a usability-oriented development process. | ** See Annex I 3c, 4c, 5, 14.6, 22.2, 22.3, 23*<br>** See Annex II 6.1a* | C1 | - | M4-LE2.1-1-1 |
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| | | - | | | | M4-LE2.1-2-1 |

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| | | - | | | | M4-LE2.1-3-1 |
| **4.2.2** | | **Standards and other directives** | | | | |
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| | | - | | | | M4-LE2.2-2-1 |
| | 3 | To know the relevant guidance documents of the FDA concerning usability and their relation to IEC 62366-1. | *The FDA provides its own guidance documents concerning 62366, specifically the guidance document titled "Applying Human Factors and Usability Engineering to Medical Devices."* | - | C1 | M4-LE2.2-3-1 |
| | 4 | To know that there are other standards on the topic of usability engineering, but these have not been harmonized. | *Examples include the ISO 9241 family of standards or ISO 14915.* | - | C1 | M4-LE2.2-4-1 |
| | 5 | To know that there is a separate certification process comparable to the CPMS concerning the topic of usability/user experience. | *CPUX program* | - | C1 | new |
| | 6 | To know the significance of IEC 60601-1-6. | *IEC 60601-1-6 is only required to be mentioned as a formality and has been essentially replaced by IEC 62366-1.* | - | C1 | new |
| | 7 | To understand the subdivision of the contents of the standard between the actual IEC 62366-1 standard and the TR 62366-2 guidance document. | *IEC 62366-1 is supplemented by TR 62366-2, which represents the instructions for use for 62366-1.* | - | C2 | new |
| **4.3** | | **Requirements of IEC 62366-1** | | | | |
| | 1 | To understand the steps of the usability-oriented development process according to IEC 62366-1. | *See IEC 62366-1, chapters 5.1 - 5.9* | C2 | - | M4-LE6.1-1-1 |

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| | 2 | To understand the interaction between the risk management process according to ISO 14971 and the usability-oriented development process according to IEC 62366-1. | *See IEC 62366-1, chapter 5.3.* | - | C2 | M4-LE6.1-2-1 |
| | 3 | To know that abnormal use is not required to be taken into account within the scope of the usability-oriented development process. | *This is explicitly excluded in the standard.* | C1 | - | M4-LE6.1-3-1 |
| **4.4** | | **From context of use to usage requirements** | | | | |
| **4.4.1** | | **Fundamentals** | | | | |
| | 1 | To be able to distinguish among stakeholder requirements, usage requirements and system requirements and place them in context. | *- There are different requirement levels.*<br>*- Usage and system requirements are tested fundamentally differently.* | C2 | - | M4-LE3.1-1-1 |
| | | - | | | | M4-LE3.1-2-1 |
| | | - | | | | M4-LE3.1-3-1 |
| | 2 | To understand the consequences that may result from inadequately defined usage requirements. | *Products are not oriented on the actual requirements of the users.*<br>*Subsequent work is necessary, no market acceptance, new product risks or even serious harm to patients/users.* | - | C2 | M4-LE3.1-4-1 |
| **4.4.2** | | **Context of use** | | | | |
| | 3 | To know the definition of "context of use." | *Definition per 9241-11:2018 3.1.15 or 9241-110:2008, 3.1* | C1 | - | |
| | 4 | To know the contents of a use specification. | ** Medical indication/medical purpose*<br>** Intended use (recommended)*<br>** Patient groups*<br>** User profile* | C1 | - | M4-LE3.2-3-1 |

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| | | | ** Usage environment*<br>** Operating principle* | | | |
| | 5 | To know that there are different user groups in the application and handling of a medical device. | *Various groups are involved in the handling and use of a medical device. These groups are listed in the usability engineering file and thus defined.* | C1 | - | M4-LE3.2-1-1 |
| | 6 | To know how to characterize the patient groups. | *Know the characteristics of a patient group per IEC 62366-1.* | - | C1 | M4-LE3.2-4-1 |
| | 7 | To know the definition of intended use. | *According to 3.9, intended use is what a user is supposed to do with the device per the specifications of the manufacturer.* | C1 | - | |
| | 8 | To understand the use of personas as a potential method for describing user profiles. | *Example of a concrete method for characterizing/describing user groups.* | - | C1 | M4-LE3.2-2-1 |
| | 9 | To know how to describe the usage environment. | *Definition 3.20 per IEC 62366-1 and explanations per 5.1 Annex A* | - | C1 | |
| | 10 | To know how to describe the operating principle. | *Convey what the operating principle is and how it can be described per 5.1 Annex A* | - | C1 | |
| | 11 | To know that some authorities call the contents of the use specification the intended purpose. | *Convey that there are different interpretations of the term "intended purpose" and that the overall contents of the use specification can be referred to as intended purpose or extended purpose.* | - | C1 | |
| | 12 | To know the most important points of an extended purpose in relation to software. | *Convey specific points concerning use specifications with software.* | - | C1 | M4-LE3.2-5-1 |
| **4.4.3** | | **Deducing the usage requirements** | | | | |

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| | 13 | To understand the relationships among the context of use, user need, and usage requirement. | | C1 | - | |
| | 14 | To understand how successful context interviews are structured. | *- Careful selection of interview partners*<br>*- Preparation of an interview guide*<br>*- Schedule sufficient time*<br>*- Create pleasant atmosphere* | - | C2 | M4-LE3.3-2-1 |
| | 15 | To know how the term "user need" is defined. | *See DAkkS guidelines or ISO/IEC 25064:2014*<br>*A user need is a necessary precondition that enables the effective fulfillment of the purpose in a context.* | C1 | - | M4-LE3.3-3-1 |
| | 16 | To understand how user needs are formulated. | *Praxiswissen User Requirements, Geis, Polkehn pg. 108:*<br>*Phrase template (user-need-type-specific): e.g., for resource user need:*<br>*The <user group> must have <necessary resource> in order to be able to <achieve outcome>.* | - | C2 | M4-LE3.3-3-1 |
| | 17 | To understand the quality criteria that form the basis of the evaluation of user needs. | *1. Formal aspect of the phrase template*<br>*2. Validation of the user need based on interview and criteria below:*<br>*- Is this user need actually covered in the context and not "made up"?*<br>*- Is the user need formulated as a precondition and purpose, i.e., does it follow the formulation template above and does it describe no system in particular?*<br>*- Does this statement apply to (nearly) all representatives of the user group?* | - | C2 | M4-LE3.3-4-1 |

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| | 18 | To know how the term "usage requirement" is defined. | *Dakks guidelines (withdrawn): a required user action on an interactive system in a manner that describes the activity, not in a manner that describes the technical realization.*<br><br>*ISO 9241-210 provides no definition, but instead refers to the specification of the usage requirements:*<br>*• Intended context of use*<br>*• Requirements derived from the user needs and context of use*<br>*• Requirements originating from relevant findings involving ergonomics or user interface, standards and guidelines*<br>*• Usability requirements and objectives, including measurable criteria for performance and satisfaction through usability in certain contexts of use*<br>*Requirements that are derived from organizational requirements that directly impact the user* | C1 | - | |
| | 19 | To understand how usage requirements are derived. | *1. Follow a process*<br>*2. Apply the following quality criteria:*<br>*1. Objectivity*<br>*2. Validity*<br>*3. Consistency* | - | C2 | M4-LE3.3-1-1 |
| **4.5** | | **User interface** | | | | |
| **4.5.1** | | **Designing a user interface** | | | | |
| | 1 | To know the contents to be included in a user interface specification. | *IEC 62366-1, chapter 5.6; IEC TR 62366-2, chapter 13* | C1 | - | M4-LE4.1-3-1 |

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| | 2 | To know the steps for designing a user interface. | *IEC 62366-2, chapter 15* | - | C2 | M4-LE4.1-1-1 |
| | 3 | To know the components of a user interface. | *ISO 9241-210: A user interface is "all components of an interactive system (software or hardware) that provide information and controls for the user to accomplish specific tasks with the interactive system."*<br><br>*Information: such as signal lights on a machine, text, images Controls: software, such as buttons, dropdown menus; machines, such as levers, handles, knobs* | - | C2 | M4-LE4.1-2-1 |
| | 4 | To know examples of requirements from UI style guides, standards and directives. | *For example, Microsoft UI style guides for different technologies, e.g., Page layout for UWP Apps: design recommendation for screen sizes*<br><br>*Examples of guides: OS X Human Interface Guidelines, iOS Human Interface Guidelines, Android Design Principles, SAP R/3 Style Guide, Java Look and Feel Design Guidelines* | - | C2 | M4-LE4.1-4-1 |
| | 5 | | | | | M4-LE4.1-5-1 |
| | 6 | | | | | M4-LE4.1-5-1 |
| **4.5.2** | | **User interface and risks** | | | | |
| | 7 | To know that characteristics related to safety and potential use errors should be identified and incorporated into the RM file. | *See IEC 62366-1:2015 + COR1:2016, chapter 5.2.* | C1 | - | |
| | 8 | To know that foreseeable hazards and hazardous | *See IEC 62366-1:2015 + COR1:2016, chapter 5.3.* | C1 | - | |

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| | | situations should be considered and incorporated into the RM file. | | | | |
| | 9 | To know that hazard-related use scenarios should be identified and incorporated into the RM file. | *See IEC 62366-1:2015 + COR1:2016, chapter 5.4.* | C1 | - | |
| | | - | | | | M4-LE4.2-1-1 |
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| **4.6** | | **Evaluation methods** | | | | |
| **4.6.1** | | **Fundamentals** | | | | |
| | 1 | To understand the difference between formative and summative evaluation. | *IEC 62366-1, chapters 5.8 and 5.9. Essentially:*<br>*- Formative: evaluation of the design during development*<br>*- Summative: objective proof that the UI can be safely used, development close-out* | C2 | - | |
| | 2 | To know that IEC 62366:2008 refers to verification and validation of usability and IEC 62366-1:2015 refers to formative and summative evaluation. | *It is important to understand this fundamental difference among various editions of the standard in the case of existing documentation.* | - | C1 | M4-LE5.3-1-1 |
| | 3 | To know the test methods for performing formative and summative evaluations. | *Cognitive walkthrough, verification against style guides, heuristics, design patterns, usability tests with prototypes of different qualities, interviews, questionnaires, usability studies in the lab.*<br><br>*Connected to learning objectives "Methods for Formative Evaluation" and "Summative Evaluation"* | - | C1 | M4-LE5.1-1-1 |
| | 4 | To know test methods for formative and summative evaluation. | *Formative: tests during development*<br>*Summative: final evaluation, usually with a usability test* | C1 | - | M4-LE5.1-2-1 |

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| | 5 | To know that test criteria are necessary for testing with test methods. | *See also 62366-2.* | - | C1 | M4-LE5.1-2-1 |
| | 6 | To know how the test criteria for the various test methods differ. | *TODO: types of test criteria* | - | C1 | M4-LE5.1-2-1 |
| **4.6.2** | | **Formative evaluation** | | | | |
| | | - | | | | M4-LE5.2-1-1. |
| | | - | | | | M4-LE5.2-2-1 |
| | | - | | | | M4-LE5.2-2-1 |
| | | - | | | | M4-LE5.2-2-1 |
| | 7 | To know which test methods can be applied in a formative evaluation. | *Cognitive walkthrough, verification against style guides, heuristics, design patterns, usability tests with prototypes of different qualities, interviews, questionnaires* | - | C1 | new |
| | 8 | To know the content and structure of a formative evaluation plan. | *IEC 62366-1, 5.7.2: Plan must address the evaluation methods being used, which part of the UI is being evaluated, and when to perform each of the UI evaluations.* | - | C1 | new |
| | 9 | To know the contents of a formative evaluation report. | *IEC TR 62366-2: contents are part of the usability engineering report. Learning objective xxx covers the report.* | - | C1 | M4-LE5.2-3-1 |
| | | | | | | M4-LE5.2-4-1 |
| **4.6.3** | | **Summative evaluation** | | | | |
| | | - | | | | M4-LE5.3-1-1 |
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| | 10 | To know which test methods can be applied in a summative evaluation. | *- Usability tests (participatory observation), normal case!*<br>*- Cognitive walkthrough, e.g., with intended users*<br>*- Review by a usability expert*<br><br>*Comparison possible with similar UIs und their usability test results (see also IEC 62366-1, 5.9)* | - | C1 | new |
| | 11 | To know the content and structure of a summative evaluation plan. | *IEC 62366-1, 5.7.3: evaluation methods, part of UI, criteria for noticeability of safety features, accompanying documentation; for usability test: test environment and methods of data acquisition.* | - | C1 | M4-LE5.3-4-1 |
| | 12 | To know the content and structure of a summative evaluation report. | *IEC 62366-1, 5.9: part of usability engineering file, evaluation of obtained data.* | - | C1 | M4-LE5.3-5-1 |
| **4.6** | | **Miscellaneous** | | | | |
| **4.6.1** | | **DIN EN 62366-1** | | | | |
| | | - | | | | M4-LE6.1-1-1 |
| | | - | | | | M4-LE6.1-1-1 |
| **4.7** | | **Documentation** | | | | |
| | 1 | To know how compliance with the 62366-1 standard is verified. | *Review of the file (see remarks in the standard concerning verification of compliance through review of usability engineering file).* | C1 | - | M4-LE6.2-1-1 |
| | 2 | To know which contents are required to be documented according to IEC 62366-1. | *IEC 62366-1, 4.2 Usability engineering file and/or IEC 62366-2, 18:*<br>*- Use specification*<br>*- Hazards, including use scenarios*<br>*- User interface specification*<br>*- Formative and summative evaluation plan/report* | C1 | - | M4-LE6.2-2-1 |
| | 3 | To know that the usability engineering file can also consist of | *Risk management file and rest of product specification (for* | C1 | - | M4-LE6.2-1-1. |

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| | | references to other documents. | *software: UI specification as part of software requirements specification).* | | | |
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## 5. Quality and document management curriculum

| chapter | ID | Learning objective | explanation | FL | AL | Reference to curriculum 2.0 |
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| **5** | | **Quality and document management** | | | | |
| **5.1** | | **Quality management** | | | | |
| **5.1.1** | | **Process-oriented approach** | | | | |
| | 1 | To understand why processes are important. | *Basic idea: clear-cut, reproducible work leads to high-quality products originally a production concept to achieve reproducibility.* | C2 | - | |
| | 2 | To know the similarities and differences between ISO 13485 and ISO 9001. | *Contents similar to those of ISO 9001, but specifically for medical devices*<br>*Responsibility of management highly important*<br>*Unlike in ISO 9001, no obligation to implement continual improvement (only for consideration as to whether it is possible/necessary).* | C1 | - | M5-LE1.1-1-1 |
| | 3 | To understand the essential requirements of ISO 13485. | *Chapters 4 through 8, each with rough description of the requirements and examples for their implementation.* | C2 | - | M5-LE1.1-1-1 |
| | 4 | To know the risk-based approach in ISO 13485. | *Necessary effort and expenditures should correspond to the risk.* | C1 | - | new |
| | 5 | To know what "management responsibility" involves according to ISO 13485. | *Chapter 5 of the standard.* | - | C1 | new |
| | 6 | To know the essential requirements that apply to the management of resources. | *Chapter 6 of the standard.* | - | C1 | new |
| | 7 | To understand the various aspects that must be taken into account during product realization | *Sub-chapters of chapter 7 of the standard.* | - | C2 | new |

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| | | according to ISO 13485. | | | | |
| | 8 | To understand that ISO 13485 also defines requirements that apply to outsourced processes. | *Specifically in chapter 4 and chapter 7.3.* | - | C2 | new |
| | 9 | To know the essential requirements that apply to measurement, analysis, and improvement. | *Chapter 8 of the standard.* | - | C1 | new |
| **5.1.2** | | **Documentation requirements that apply to the quality management system** | | | | |
| | 10 | To know the term "documented procedure." | *Procedural instructions (typical terms include process specifications, SOPs, work instructions, and other terms).* | C1 | - | new |
| | 11 | To understand the typical structure of a documented quality management system. | *Documentation pyramid different degrees of detail and target groups, depending on level.* | - | C2 | M5-LE1.2-1-1 |
| | 12 | To know which procedures are already required to be documented according to ISO 9001. | *Control of documents and records*<br>*Internal audits*<br>*Control of defective products*<br>*Control of corrective actions and preventive actions (CAPAs)* | C1 | - | M5-LE1.2-1-1. |
| | 13 | To know that ISO 13485 prescribes a series of additional procedures that must be documented. | *Examples only.* | C1 | - | M5-LE1.2-1-1. |
| | 14 | To know which additional procedures are required to be documented according to ISO 13485. | *See ISO 13485.* | - | C1 | M5-LE1.2-1-1. |

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| | 15 | To understand the correlation between ISO 13485 and IEC 62304 in relation to the documents to be created. | *ISO 62304 prescribes the activities to be planned and documented during SW development. In particular, a SW development plan is required, in which the documents to be created must be listed.*<br>*ISO 13485 requires that this take place using a controlled process. As a result, there are often document templates and procedural instructions/SOPs that are then merely referenced in the SW development plan.* | - | C2 | M5-LE1.2-1-1 |
| **5.2** | | **General requirements that apply to the documentation** | | | | |
| **5.2.1** | | **Lifecycle of documents and records** | | | | |
| | 1 | To understand the purpose for which documentation should be created. | *Knowledge management, coordination, proof* | C2 | - | M5-LE2.2-1-1 |
| | 2 | To know the difference between a document and a record. | *One-time vs. versioned document, term already defined in ISO 9001.* | C1 | - | M5-LE1.2-1-1 |
| | 3 | To be able to provide examples of documents and records in SW development. | *Requirements specification, test record.* | - | C2 | new |
| | 4 | To know the lifecycle of documents. | *Creation, approval, access, archiving.* | C1 | - | M5-LE2.1-1-1 |
| | 5 | To understand the status of each document at each phase of its lifecycle. | *Creation: draft, in review*<br>*Approval: released*<br>*Access: released*<br>*Archiving: released, obsolete* | - | C2 | new |
| | 6 | To understand the necessity and difficulties of long-term archiving. | *Storage periods (see also MDR), risks (disintegration of paper, fire, outdated SW), PDF/A as recognized format.* | - | C2 | M5-LE2.1-1-1 |
| | 7 | To understand the purpose and benefit of a document plan. | *List that provides information about what was current and when* | - | C2 | M5-LE2.2-1-4 |

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| | | | *concerning each specific product.* | | | |
| | 8 | To know what a document management system (DMS) is. | *Software that manages the document plan and enables controlled access.* | - | C1 | M5-LE2.1-1-1 |
| **5.2.2** | | **Requirements that apply to the creation of documents** | | | | |
| | 9 | To know the formal requirements that apply to documents. | *Author, version, date, status, history.* | C1 | - | M5-LE2.2-1-2 |
| | 10 | To know a typical document structure. | *Scope, purpose etc; more detailed rules useful in a procedural instruction.* | C1 | - | M5-LE2.2-1-3 |
| | 11 | To understand the requirements that apply to the creation of documents defined in ISO 13485. | *What is the document required to include? How are the documents created (e.g., as scanned, handwritten records)? Who is the author? When must a document undergo a review and how?* | - | C2 | M5-LE2.1-1-1 . |
| **5.2.3** | | **Requirements that apply to the review and release of documents** | | | | |
| | 12 | To understand the difference between review and release. | *Review comes first, typically by several people. Release is an official act following successful review of the latest revision.* | - | C2 | M5-LE2.1-1-1 |
| | 13 | To understand where the rules can be found that must be observed when reviewing a document. | *Company-/project-specific Must be specified in a documented procedure, as required according to ISO 13485.* | - | C2 | M5-LE2.1-1-10. |
| | 14 | To know the typical review procedures for documents and records. | *Dual control principle, walkthrough, inspection.* | - | C1 | new |
| | 15 | To understand the requirements of the FDA that apply to electronic documents and records. | *21 CFR Part 11* | - | C2 | M5-LE2.1-1-11 |
| | 16 | To understand the difference between a digital signature, | *Per definition in 21 CFR 11.* | - | C2 | M5-LE2.1-1-12 |

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| | | electronic signature, and electronic record. | | | | |
| | 17 | To know what is and what is not typically signed electronically. | *Often: code reviews, test records, individual work items (requirements, test records)*<br>*More rarely: specifications, plans, reports*<br>*Almost never: declarations of conformity and other "highly official" documents.* | - | C1 | new |
| **5.3** | | **Required documentation** | | | | |
| **5.3.1** | | **Fundamentals** | | | | |
| | 1 | To know which files are required for documentation. | *Risk management file, usability engineering file, development documentation, technical documentation* | C1 | - | M5-LE3.1-1-1 |
| | 2 | To understand which documents are typically found in which file. | *Recap of the 3 files (without technical documentation) that have already been covered in the previous modules.* | C2 | - | new |
| | 3 | To understand how redundancies can be avoided. | *Outsource intended purpose, include usability in risk analysis.* | - | C2 | M5-LE3.1-1-2. |
| | 4 | To understand the impact of the safety category on the documentation necessary. | *IEC 62304 [class A, B, C]*<br>*FDA LoC* | C2 | - | new |
| | 5 | To understand how the documentation can be incorporated into agile processes. | *Write iteratively and release individual work items; final sprint to official release*<br>*AAMI/TIR45.* | - | C2 | new |
| - | | **5.3.2 Risk management file** | | | | **5.3.2 Risikomanagementakte** |
| | 6 | - | | | | M5-LE3.2-1-1 |
| | 7 | - | | | | M5-LE3.2-1-2 |
| | 8 | - | | | | M5-LE3.2-1-3 |
| - | | **5.3.3 Usability engineering file** | | | | **5.3.3 Gebrauchstauglichkeitsakte** |
| | 9 | - | | | | M5-LE3.3-1-1 |
| | 10 | - | | | | M5-LE3.3-1-2 |
| - | | **5.3.3 Usability engineering file** | | | | **5.3.4 Dokumentation der Softwareentwicklung** |

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| | 11 | - | | | | M5-LE3.4-1-1 |
| | 12 | - | | | | M5-LE3.4-1-2 |
| **5.3.2** | | **Technical documentation** | | | | |
| | 13 | To understand the objective of the technical documentation. | *To provide proof of the usability and safety of the product.* | - | C2 | M5-LE3.5-1-1 |
| | 14 | To know the contents of the technical documentation. | *See MDR Annex II.* | - | C1 | M5-LE3.5-1-1 |
| | 15 | To know the contents of the technical documentation in detail. | *Complete list.* | - | C1 | new |
| | 16 | To understand how the review of the technical documentation by the notified body takes place. | *What is reviewed and when? What happens in the case of deviations/nonconformities? How can I ensure a smooth workflow?* | - | C2 | new |
| **5.4** | | **Required documentation outside the EU** | | | | |
| **5.4.1** | | **FDA vs. EU** | | | | |
| | 1 | To understand the similarities and differences between the documentation requirements of the FDA and the EU. | | - | C2 | new |
| | 2 | To understand the special requirements of the FDA that apply to document control. | *See explanations of LP 2.1.* | - | C2 | M5-LE4.1-1-2 |
| | 3 | To know the terms "DHF," "DMR," and "DHR." | *DHF: Design History File*<br>*DMR: Device Master Record*<br>*DHR: Design History Record* | - | C1 | M5-LE4.1-1-3 |
| | 4 | To understand what the differences are between DHF, DMR and DHR. | *See explanations of LP 2.1.* | - | C2 | M5-LE4.1-1-6 |
| **5.4.2** | | **Summary Technical Documentation (STED)** | | | | |

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| | 5 | To understand the significance of the summary technical documentation (STED). | *A folder structure; each country specifies what it wants to see.* | - | C2 | new |
| | 6 | To know that STED is an initiative of the IMDRF. | *(self-explanatory)* | - | C1 | new |
| | 7 | To know the countries that recognize STED. | | - | C1 | new |
| | 8 | To understand the structure of STED. | *With example table, such as for Canada.* | - | C2 | new |
| **5.5** | | **Medical Single Audit Program (MDSAP)** | | | | |
| | 1 | To understand the significance of the medical single audit program (MDSAP). | *One audit, 5 countries.* | - | C2 | new |
| | 2 | To know the countries that are participants in the MDSAP. | *USA, Canada, Japan, Australia, Brazil* | - | C1 | new |

## 6. Medical informatics curriculum

| chapter | ID | Learning objective | explanation | FL | AL | Reference to curriculum 2.0 |
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| **6** | | **Medical informatics** | | | | |
| **6.1** | | **Informatics in the healthcare system** | | | | |
| **6.1.1** | | **Fundamentals** | | | | |
| | 1 | To know typical agents in the healthcare system. | *Patients, doctors, clinics/hospitals, pharmacies, rehabilitation centers, nursing, etc. Country-specific contents, such as the Association of Statutory Health Insurance Physicians in Germany and the usual supplemental insurance in France can be mentioned, but are not relevant to the exam.* | - | C1 | M6-LE1.1-1-1 |
| | 2 | To understand current trends in the healthcare system. | *Miniaturization, eHealth, telemedicine, artificial intelligence in short: increasing digitalization and thus increasingly more software* | - | C2 | M6-LE1.4-4-1 |
| **6.1.2** | | **Data in the healthcare system** | | | | |
| | 3 | To understand why data are collected in the healthcare system. | *For certificates (illness, death), statistics, research For purposes of invoicing (cashflow) More recently also for "in silicio" analyses (findings from Big Data, AI)* | - | C2 | M6-LE1.5-1-1 |
| | 4 | To understand the diversity of data in the healthcare system. | *Master data, insurance data, medical history, findings, diagnoses, therapies, longitudinal documentation, metadata* | - | C2 | M6-LE1.5-1-1 |
| | 5 | To know examinations that generate especially large volumes of data. | *Genetic tests, all tests with high-resolution images, longitudinal data over long periods (e.g., using monitoring sensors, ventilators).* | - | C2 | M6-LE1.5-1-2 |
| | 6 | To know the forms of medical documentation. | *structured/unstructured analog/digital* | - | C1 | M6-LE2.1-1-1 |

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| | 7 | To understand the benefits of structured, digitally available information. | *Easy to transmit, automated analyses possible, traceability/archiving* | - | C2 | M6-LE2.1-1-1 |
| | 8 | To understand the challenges of data protection. | *Data should be rapidly available, but only accessible to authorized persons.*<br>*Data must be stored.*<br>*Data are worth money and thus attractive to thieves.* | - | C2 | new |
| **6.1.3** | | **Information systems** | | | | |
| | 9 | To understand the essential tasks of information systems. | *Classification of tasks according to Haas*<br>*Alternatively: Providing the right information at the right time and the right place in the right form to authorized persons.* | - | C2 | M6-LE3.1-1-1 |
| | 10 | To know the information systems typically in use at hospitals and medical practices. | *KIS, LIS, RIS, PACS*<br>*medical practice information systems* | - | C1 | M6-LE3.2-1-1 |
| **6.2** | | **Interoperability** | | | | |
| **6.2.1** | | **Principles of interoperability** | | | | |
| | 1 | To know the most important reasons why interoperability is pursued. | *Accelerate workflows, prevent duplicate tests, save money, provide cross-sector data.* | - | C1 | M6-LE4.1-1-1 |
| | 2 | To understand the factors by which interoperability is impeded at the technical level. | *Heterogeneous systems (different manufacturers) and thus different data formats, protocols or storage media* | - | C2 | M6-LE4.1-1-1 |
| | 3 | To understand the factors by which interoperability is impeded at the content level. | *Last name not common in all cultures, transcribed characters*<br>*homonyms, synonyms* | - | C2 | M6-LE4.1-1-1 |
| | 4 | To know the four interoperability levels. | *Structural, syntactic, semantic, organizational* | - | C1 | M6-LE4.2-1-1 |
| **6.2.2** | | **Classification systems** | | | | |
| | 5 | To understand the difference between "terminology," "classification," and "taxonomy." | *Terminology = dictionary/glossary*<br>*Classification = categorization into classes*<br>*Taxonomy = hierarchical classification* | - | C2 | M6-LE2.2-1-1 |

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| | 6 | To understand the difference between a dictionary, thesaurus, and ontology. | *Dictionaries contain definitions*<br>*Thesauruses establish relationships among terms (e.g., synonyms)*<br>*Ontologies model domains of discourse* | - | C2 | M6-LE2.2-1-1. |
| | 7 | To know the objective and use of ICD-10. | *Taxonomy for the coding of diagnoses and causes of death.* | - | C1 | M6-LE2.3-1-1 |
| | 8 | To know the publisher of the ICD-10 catalog. | *Essentially, the WHO (in Germany, the DIMDI also, but this is not relevant to the exam).* | - | C1 | M6-LE2.3-1-1<br>M6-LE2.2-1-1 |
| | 9 | To know the objective and use of LOINC. | *Classification system that is used to code results, such as lab values, vital parameters, physical examination findings, etc.* | - | C1 | M6-LE2.4-1-1 |
| | 10 | To know the data coded in LOINC. | *Component (analyte), measured characteristic (unit of measure), time and date, sample type (system), scale, measurement method* | - | C1 | M6-LE2.4-1-1 |
| | 11 | To know the publisher of LOINC. | *Regenstrief Institute, Indianapolis* | - | C1 | M6-LE2.4-1-1 |
| | 12 | To understand that there are other classification systems. | *Examples in Germany include ATC, OPS, SNOMED (the response is country-specific, but not the principle)* | - | C2 | M6-LE2.5-1-1<br>M6-LE2.6-1-1 |
| **6.2.3** | | **Interoperability of medical data** | | | | |
| | 13 | To know the objective and use of DICOM. | *Cross-vendor, standardized data format* | C1 | - | M6-LE6.1-1-1 |
| | 14 | To know the information that is standardized using DICOM. | *This essentially involves patient information (name, age, etc.) and images*<br>*It also standardizes commands and messages also for searching, printing, and ordering tests.* | C1 | - | M6-LE6.3-1-1 |
| | 15 | To understand the structure of DICOM files. | *Binary format*<br>*Data tag, data type, value length, value* | C2 | - | M6-LE6.2-1-1<br>M6-LE6.2-2-1 |
| | 16 | To understand the significance of a DICOM Conformance Statement for interoperability. | *Reliable certification of compatibility* | - | C2 | M6-LE6.1-1-1 |

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| | 17 | To know the terms "IOD" and "IU." | *See Glossary.* | - | C1 | M6-LE6.2-2-1 |
| | 18 | - | | - | - | M6-LE6.2-2-1 |
| | 19 | To understand that the DICOM standard defines the attributes, modules and information entities that an IOD of a certain type (e.g. CT image) comprises. | *Per standard.* | - | C2 | M6-LE6.2-2-1 |
| | 20 | To understand the DICOM term "SOP." | *SOP: Service Object Pair*<br>*Definition and use per standard* | - | C2 | M6-LE6.3-1-1 |
| | 21 | To understand the DICOM term "SCU." | *SCU: Service Class User*<br>*Definition and use per standard* | - | C2 | M6-LE6.3-1-1 |
| | 22 | To understand the DICOM term "SCP." | *SCP: Service Class Provider*<br>*Definition and use per standard* | - | C2 | M6-LE6.3-1-1 |
| | 23 | To understand the DICOM term "DIMSE." | *DIMSE: DICOM Message Service Element*<br>*Definition and use per standard* | - | C2 | M6-LE6.3-1-1 |
| **6.2.4** | | **Interoperability of messages** | | | | |
| | 24 | To know the objective and use of HL7 V2. | *Interoperability within an institution (e.g., hospital)*<br>*V2 is the version number*<br>*Not to be confused with HL7 V3, which has yet to become well established due to a lack of backward compatibility.* | - | C1 | M6-LE5.1-1-1 |
| | 25 | To understand the structure of an HL7 V2 message. | *ASCII format*<br>*1 message = many segments that are separated by a line break (CR)*<br>*Each segment consists of fields.*<br>*The exact structure is defined in the standard.* | - | C2 | M6-LE5.2-2-1 |

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| | 26 | To be able to break down an HL7 message into its components. | *The first field of each segment is the segment ID and specifies the type of segment involved. Examples of segment IDs include (Message Header), PID (Patient Identification), and EVN (Event). The HL7-V2 standard defines the optional and mandatory fields for each segment type. In addition, the standard defines the data type for each field. Field 9 of the MSH segment specifies the so-called message type, which in turn enables recognition of the reason for the triggering of the message and the information it involves. The participants receive an example and, if necessary, additional information from the standard for the exercise.* | - | C3 | M6-LE5.2-2-1<br>M6-LE5.2-3-1 |
| **6.2.5** | | **Interoperability of processes** | | | | |
| | 27 | To know the objective and use of HL7 V2. | *IHE: Integrating the Healthcare Enterprise*<br>*Originally an attempt to standardize workflows*<br>*Did not become established*<br>*Good basis for validation* | C1 | - | new |
| **6.2.6** | | **Practical implementation of interoperability** | | | | |
| | 28 | To understand how syntactic interoperability is achieved using standards (DICOM, HL7). | *Standard defines how data stream is structured.* | - | C2 | new |
| | 29 | To understand how semantic interoperability is achieved via the integration of classification systems (code systems, identification systems). | *A lot of information coded in a few bytes, which both sides understand equally.* | - | C2 | M6-LE5.2-4-1 |

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| | 30 | To know the interoperability level where ICD-10, LOINC, DICOM, and HL7 are located. | *Essentially syntactically and semantically*<br>*Delineation not clear-cut* | - | C2 | M6-LE4.2-1-1 |

## 7. IT security curriculum

| chapter | ID | Learning objective | explanation | FL | AL | Reference to curriculum 2.0 |
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| **7** | | **IT security** | | | | |
| **7.1** | | **General requirements** | | | | |
| | 1 | To know the requirements in the MDR that apply to IT security. | | C1 | - | new |
| | 2 | To know that there is no harmonized standard for IT security. | | C1 | - | new |
| | 3 | To be able to name established standards involving IT security: | *Germany:*<br>** Guidelines of the BSI for health applications*<br>** IT security guidelines of the notified bodies/Johner Institut*<br>** Annexes to the DiGAV International:*<br>** Etc.* | C1 | - | new |
| | 4 | To know that confidentiality, availability, and integrity are the three essential protection objectives of IT security. | *All necessary and required measures are ultimately attributable to these three protection objectives.* | C1 | - | new |
| | 5 | To know that, unlike data protection, IT security involves not just personal data. | *Data protection and IT security may often go hand-in-hand, but are clearly distinguishable.* | C1 | - | new |
| | 6 | To know that measures are necessary within the organization and measures are necessary involving the devices in order to ensure IT security. | *Additional, concrete learning objectives involving both types of measures are below.* | C1 | - | new |
| | 7 | To understand typical attack scenarios on the three protection objectives: confidentiality, availability, and integrity. | *Examples include STRIDE model*<br>** Spoofing (attacks authenticity)*<br>** Tampering (attacks integrity)*<br>** Repudiation (attacks non-repudiability)*<br>** Information disclosure (attacks confidentiality)*<br>** Denial of service (attacks availability)*<br>** Elevation of privilege (attacks authorization)* | C2 | - | new |
| | 8 | To understand that IT security cannot be considered in | | C2 | - | new |

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| | | isolation, but instead must be considered within existing processes. | | | | |
| | 9 | To know that a manufacturer must designate the roles associated with IT security and prove their required competences. | | C1 | - | new |
| | 10 | To know that the manufacturer must know the requirements that apply to IT security in all target countries, in which the system is intended to be placed on the market. | | - | C1 | new |
| **7.2** | | **Requirements that apply to processes** | | | | |
| | 1 | To know that IT security must be considered within the scope of risk management. | *Here, the connection to risk management must be clearly established.* | C1 | - | new |
| | 2 | To know that it is necessary to consider other IT systems that interact with the system with regard to the three protection objectives. | *Here, convey merely a basic understanding; concrete requirements are covered in the AL learning objective.* | C1 | - | new |
| | 3 | To understand the requirements that apply to the documentation of the other IT systems that interact with the system. | ** Interacting IT systems must be identified.*<br>** Data interfaces must be documented.*<br>** The functions to be provided via the data interface must be documented.*<br>** The protocols, with which the system interacts, must be described.*<br>** The functions and interfaces must be considered in risk management.*<br>** Etc.* | - | C2 | new |
| | 4 | To know that it is necessary to identify the user roles interacting with the system. | *Here, convey merely a basic understanding; concrete requirements are covered in the AL learning objective.* | C1 | - | new |
| | 5 | To understand the requirements that apply to the documentation of the roles that interact with the system. | ** Interacting users/roles must be identified*<br>** The corresponding functions that the systems/roles are permitted to execute must be identified*<br>** Etc.* | - | C2 | new |

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| | 6 | To know that it is necessary to consider the data managed by the system with regard to the three protection objectives. | *Here, convey merely a basic understanding; concrete requirements are covered in the AL learning objective.* | C1 | - | new |
| | 7 | To understand the requirements that apply to the documentation of the data managed by the system. | ** The data managed by the system must be documented.*<br>** The data managed by the system must be evaluated with regard to its worthiness for protection and confidentiality.*<br>** Risk management must consider the impacts of situations in which data that are especially worthy of protection are no longer protected.*<br>** Etc.* | - | C2 | new |
| | 8 | To know that it is necessary to coordinate the test activities and ensure that they cover the three protection objectives. | *Here, convey merely a basic understanding; concrete requirements are covered in the AL learning objective.* | C1 | - | new |
| | 9 | To understand the specific requirements that apply to the test activities. | *Tests of known vulnerabilities, such as*<br>** Port scans*<br>** Penetration tests*<br>** Testing of interfaces with SOUP components*<br>** Etc.* | - | C2 | new |
| | 10 | To know that it is necessary to consider the process of system distribution and installation with regard to the three protection objectives. | *Here, convey merely a basic understanding; concrete requirements are covered in the AL learning objective.* | C1 | - | new |
| | 11 | To understand the requirements that apply to system distribution and installation. | ** Ensure that the system contains no malicious code before delivery.*<br>** Updates and patches must be provided based on a defined plan.*<br>** Criteria must be established as the basis for verifying whether an installation was successful.*<br>** Etc.* | - | C2 | new |
| | 12 | To know that is it necessary to consider the process of market surveillance. | *Here, convey merely a basic understanding; concrete requirements are covered in the AL learning objective.* | C1 | - | new |

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| | 13 | To understand the requirements that apply to IT security within the scope of market surveillance. | ** There is a post-market surveillance plan.*<br>** The IT security information to be collected during market surveillance is defined.*<br>** The sources, from which information is to be collected, are defined.*<br>** The methods for analyzing the information are defined.*<br>** OTS and SOUP components are monitored for newly identified issues.*<br>** The security of cryptographic methods is regularly verified.*<br>** Etc.* | - | C2 | new |
| **7.3** | | **Requirements that apply to the product** | | | | |
| | 1 | To understand the requirements that apply to product authentication. | ** Users and other IT systems must be authenticated on the system.*<br>** No standard password is used.*<br>** There are guidelines for passwords (e.g., minimum length, use of special characters, etc.).*<br>** There is a guideline for (temporarily) blocking users and systems after multiple failed log-in attempts.*<br>** Etc.* | - | C2 | new |
| | 2 | To know that it is necessary to define and implement a role concept for the system. | *Here, convey merely a basic understanding; concrete requirements are covered in the AL learning objective.* | C1 | - | new |
| | 3 | To understand the requirements that apply to the implementation of a role concept. | ** A role must be assigned to each user and each system to be used.*<br>** Users are only permitted to execute functions for which they are authorized based on their role.*<br>** (Only) authorized users are permitted to block or delete other users and systems.*<br>** (Only) authorized users are permitted reset the passwords of other users.*<br>** It is not possible for a user* | - | C2 | new |

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| | | | *to change his or her own role or permissions.* | | | |
| | 4 | To know that it is necessary to consider any handling of data with regard to the three protection objectives. | *Here, convey merely a basic understanding that each action (CRUD, Create/Read/Update/Delete) must be taken into consideration. Concrete requirements are covered in the AL learning objective.* | C1 | - | new |
| | 5 | To understand the requirements that apply to handling data. | ** All security-relevant data are transmitted and saved in encrypted form only.*<br>** All entries by users or other systems are checked based on defined criteria before they are further processed.*<br>** In the case of a client-server architecture, all calculations and checks are performed on the server side.*<br>** The integrity of (especially critical) data is ensured (e.g., using checksums)*<br>** Time-critical data relevant to patient safety/security are not wirelessly transmitted.*<br>** Proven libraries are used for cryptographic methods.* | - | C2 | new |
| | 6 | To know that it is necessary to reach a decision concerning the need for logs. | *Here, convey merely a basic understanding; concrete requirements are covered in the AL learning objective.* | C1 | - | new |
| | 7 | To understand the requirements that apply to logs. | ** The system maintains a log of essential activities, including users and times*<br>** It is ensured that the time noted in the log is correct.*<br>** The log is read-only.* | - | C2 | new |
| | 8 | To know that the accompanying documentation also plays a major role in ensuring IT security. | *Here, convey merely a basic understanding; concrete requirements are covered in the AL learning objective.* | C1 | - | new |

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| | 9 | To understand the requirements that apply to the accompanying documentation. | ** The intended IT environment is described in the accompanying documentation.*<br>** The accompanying documentation includes instructions for the necessary activities that involve IT security and that must be performed by the users (updates, patches etc.)*<br>** The accompanying documentation includes instructions for handling lost or stolen authentication elements.*<br>** The accompanying documentation includes the contact information of the manufacturer.*<br>** The accompanying documentation includes any restrictions or specifications concerning anti-malware programs.*<br>** The accompanying documentation includes a technical description of the product.*<br>** Etc.* | - | C2 | new |