UDecide

MANAGEMENT OF MDR   
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SCOPE: This document contains the projects interpretation and management of the Medical Device Regulation (MDR 2017:745).

REFERENCES:

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| 1.0 | Sigrid Stang & Sofie Bjørn | 11-04-2021 | First version of interpretation and management of the Medical Device Regulation (MDR 2017:745). |
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APPROVAL:

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| **Where in MDR 2017-745** | **What the chapter/article is about** | **Our interpretation and management of the regulation** | **Reference to other standards/documents/annexes** |
| **Chapter 1**, article 1 and article 2 | MDR definitions | Used to define our product  (decision support system)  in accordance to the medical device regulation |  |
|  | Article 2(1)  “Medical device”  and  *“Medical Device Software (MDSW)* | Because the decision support system is software with medical purpose for prediction of treatment, the decision support system is defined as a “Medical device”  The decision support system is a “Medical Device Software (MDSW)**”**  because it is intended to be used in combination with the purpose of a medical device  To be qualified as a MDSW, the decision support system must have a medical purpose and the product must fulfil article 2(1) of Regulation (EU) 2017/745 – MDR. Furthermore software which is intended to process, analyse, create or modify medical information is qualified as a medical device software. | MDCG 2019-11 page: 4, 6 and 7 |
|  | Article 2(2)  “Accessory for a medical device” | The decision support system is an “Accessory for a medical device” because it is intended to be used together with one particular medical device (UCon) | MDCG 2019-11 page: 3 |
|  | Article 2(4)  “active device” | The decision support system shall be regarded as an “active device” because all software is categorized as an active device. | MDCG 2019-11 page: 4 |
| **Chapter 2**, article 5 | Regarding placing the product on the market and putting it into service | Used to identify the needed requirements for placing the product on the market |  |
|  | Article 5(1) | The decision support system may only be placed on the market,  if it complies with the MDR. This shall be in accordance with the intended purpose of the decision support system. |  |
|  | Article 5(2) | The  decision support system shall meet the general safety and performance requirement, which is set out in annex 1 in MDR 2017-745.  Demonstration of conformity with annex 1 shall include clinical evaluation in accordance with article 61 | MDR 2017-745  Annex 1    MDR 2017-745  article 61 |
| **Chapter 2**, article 10 | Regarding the general obligations of manufactures | Used to identify which general obligations we have as a manufacturer of af medical device |  |
|  | Article 10(1) | The manufacturer shall ensure that the product is designed and manufactured in accordance with the MDR. |  |
|  | Article 10(2) | The manufacturer shall have a risk management which is described in annex I section 3. | MDR 2017-745  Annex I(3) |
|  | Article 10(4) | The manufacturer shall work out technical documentation which shall include the elements described in annex II and annex III. | MDR 2017-745  Annex II and Annex III |
|  | Article 10(6) | The manufacturer shall draw up an EU declaration of conformity in accordance to article 19.  The manufacturer shall use the CE marking of conformity as described in article 20. | MDR 2017-745 article 19  MDR 2017-745 article 20 |
| Chapter 2 | Article 10(9)  Quality Management System | The manufacturer shall establish, document, implement, maintain, keep up to date and continually improve a quality management system (QMS). The QMS shall cover all parts of the manufacturers organisation concerning structures, processes, procedures and devices. A part of the QMS is a risk management, which is set out in annex 1 section 3. | ISO13485  MDR 2017-745  Annex I(3) |
|  | Article 10(10) | The manufacturer shall implement post-market surveillance (PMS) in according to article 83 |  |
|  | Article 10(13) | The manufacturer shall have a system for reporting incidents in accordance to article 87 and 88 | MDR 2017-745  Article 87 and 88 |
| **Chapter 2**, article 14 |  |  |  |
| **Chapter 2**, article 19 |  |  |  |
| **Chapter 2**, article 20 |  |  |  |
| **Chapter 3**, article 25 |  |  |  |
| **Chapter 3**, article 32 |  |  |  |
| **Chapter 5**, article 51 |  |  |  |
| **Chapter 5**, article 52 |  |  |  |
|  | stk 1  stk 4  stk 6 |  |  |
| **Chapter 6**, article 61 |  |  |  |
|  | stk 1  stk 11 |  |  |
| **Chapter 7**, article 83 |  |  |  |
|  | stk 1  stk 2  stk 3 |  |  |
| **Chapter 7**, article 84 |  |  |  |
| **Chapter 7**, article 86 | stk 1 |  |  |
| **Chapter 7**, article 87+88+89+90 |  |  |  |
| **Chapter 7**, article 93 |  |  |  |
| **Chapter 9**, article |  |  |  |
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| **Where in MDR 2017-745** | **What the chapter/article is about** | **Our interpretation and management of the regulation** | **Reference to other standards/documents/annexes** |
| **Annex 1** | General safety and performance requirements |  |  |
| **Chapter 1 (s. 96 i MDR-PDF)** | **GENERAL REQUIREMENTS**  1 | The device shall be designed to perform the intended purpose.  It shall be safe and effective, and not compromise the health and safety of patients or users.  The potential risk shall be acceptable when weighted against the benefits to the patient. |  |
|  | 2 | Minimise risks as much as possible without affecting the benefit-risk ratio. |  |
|  | 3 | “Manufacturers shall establish, implement, document and maintain a risk management system. “ | ISO 14971:2019 |
|  | 4 | The manufacturer shall control the risks so that the residual risks are judges acceptable. |  |
|  | 5 | The manufacturer shall reduce risks related to user errors. |  |
| **Chapter 2** | REQUIREMENTS REGARDING DESIGN AND MANUFACTURE  17 - electronic programmable systems | The software “shall be designed to ensure repeatability, reliability and performance in line with their intended use.”  “The software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation. “  The software shall be designed to fit the specific features of the platform in the environment (e.g. Ipad)  The manufacturer shall set out requirements for hardware, IT-security (including protection against unauthorized access), to make sure the software can be run as intended. |  |
| **Chapter 3** | REQUIREMENTS REGARDING THE INFORMATION SUPPLIED WITH THE DEVICE  23.1 + 23.2 | The device shall be labeled with identification-information about the manufacturer and of the device.  23.2 is a list of all the things the label shall include |  |
|  | 23.4 - instructions for use | Following information shall be included in instructions for use:   1. name of device, information about manufacturer, where the device is applicable, storage/handling conditions 2. Intended purpose 3. Expected clinical benefits 4. Safety and clinical performance 5. … 6. …. |  |
| **Annex 2** | TECHNICAL DOCUMENTATION | “The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex. “ |  |
|  |  | Annex 2 contains the following topics:   * Device description and specification * INFORMATION TO BE SUPPLIED BY THE MANUFACTURER * DESIGN AND MANUFACTURING INFORMATION * GENERAL SAFETY AND PERFORMANCE REQUIREMENTS * BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT * PRODUCT VERIFICATION AND VALIDATION |  |
| **Annex 3** | TECHNICAL DOCUMENTATION ON PMS | “The technical documentation on post-market surveillance to be drawn up by the manufacturer in accordance with Articles 83 to 86 shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements described in this Annex.” |  |
|  | 1.1 | The manufacturer shall have a plan for PMS in accordance to article 84. The requirements for the PMS are described in 1.1 a and 1.1 b. | MDR 2017-745 Article 84 |
| **Annex 4** | EU DECLARATION OF CONFORMITY |  |  |
|  |  | The EU declaration of conformity shall contain all of the following information:   1. Name, registered trade name or registered trademark. 2. A statement that the EU-declaration is under responsibility of the  manufacturer. 3. The basic UDI-DI 4. Product information to identify and track the device. 5. Risk class 6. A statement that the device is in conformity with EU-declarations. 7. References to common specifications 8. ID-number of the  notified body 9. Additional info 10. Place and date of issue + name and function of the persons who signed |  |
| **Annex 5** | CE MARKING OF CONFORMITY |  |  |
|  |  | The CE marking shall consist of the initials CE - in the correct proportions. |  |
| **Annex 6** | UDI | “INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLES 29(4) AND 31, CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH THE UDI-DI IN ACCORDANCE WITH ARTICLES 28 AND 29, AND THE UDI SYSTEM“ |  |
|  |  | Part A: “INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLES 29(4) AND 31”  Part B: “CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH THE UDI-DI IN ACCORDANCE WITH ARTICLES 28 AND 29”  Part C: “THE UDI SYSTEM” |  |
| **Annex 7** | REQUIREMENTS TO BE MET BY NOTIFIED BODIES | Primarily aimed at the notified body - not that relevant for us, because we are not the notified body. |  |
|  | 1.2 | The notified body shall be an independent third-party body of the manufacturer and other stakeholders (no conflicts of interest). |  |
| **Annex 8** | CLASSIFICATION RULES |  |  |
| **Chapter 1** | DEFINITIONS SPECIFIC TO CLASSIFICATION RULES  2.5 | “‘Active device intended for diagnosis and monitoring’ means any active device used, whether alone or in combination with other devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.” |  |
| **Chapter 2** | IMPLEMENTING RULES  3.1 | The classification of the device is based on the intended purpose |  |
|  | 3.3 | “Software, which drives a device or influences the use of a device, shall fall within the same class as the device. If the software is independent of any other device, it shall be classified in its own right. “ |  |
| **Chapter 3** | CLASSIFICATION RULES | Rule 11:  Our decision support system is related to diagnosis and therapeutic purposes, and does not have an impact on decisions that can cause death or “an irreversible deterioration of a person's state of health”. Therefore it is classified as IIa - based on rule 11. |  |
| **Annex 9** | CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION |  |  |
| **Chapter 1** | QMS | “The manufacturer shall establish, document and implement a quality management system as described in Article 10(9) and maintain its effectiveness throughout the life cycle of the devices concerned. The manufacturer shall ensure the application of the quality management system as specified in Section 2 and shall be subject to audit, as laid down in Sections 2.3 and 2.4, and to surveillance as specified in Section 3. “ |  |
|  | 2.1 | The QMS-application shall be approved by a notified body, and shall include the following:   * Name and address  of manufacturer * Information on the device * …… * …... |  |
|  | 2.2 | QMS-implementation shall ensure compliance with MDR. All requirements used for the QMS shall be documented in a systematic approach in the form of a quality manual. |  |
|  | 2.3 | The notified body shall audit the QMS - furthermore the technical documentation shall be audited when the device is class IIa or IIb.  “If the quality management system conforms to the relevant provisions of this Regulation, the notified body shall issue an EU quality management system certificate” |  |
|  | 2.4 | The notified body shall be informed if there are substantial changes to the QMS. |  |
|  | 3.x | For devices classified as IIa, IIb or III further surveillance-assessments are required.  The notified body shall periodically - at least once a year - make a QMS-assessment. |  |
| **Annex 10** | CONFORMITY ASSESSMENT BASED ON TYPE-EXAMINATION |  |  |
|  | 2 | The manufacturer shall make an application for assessment with a notified body - the application shall include ….. | MDR 2017-745 - ANNEX II and III |
| **Annex 14** | CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP |  |  |
|  | Part A - 1 | The manufacturer shall plan a clinical evaluation, including the following:   * … * … * ... |  |
|  | Part B - POST-MARKET CLINICAL FOLLOW-UP | PMCF is a process to continuously update the clinical evaluation. PMCF shall be addressed in the PMS.  Part B includes a list of elements the PMCF shall include. | Article 61  Annex 14 - part A |
| **Annex 15** | CLINICAL INVESTIGATIONS | Clinical investigations are not relevant for the development of our decision support system at the moment. |  |
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