Medical Device Regulation: A Checklist for Preparation

The Medical Device Regulation (MDR) changes the legal framework for medical devices in Europe. The MDR became fully applicable beginning in May 2021. The transition period from the MDD to the MDR was originally scheduled to last until May 2024. But the EU published new legislation that extends the transition period (upon meeting certain criteria) to December 2027 or December 2028, depending on the class of the device. This extension opens a window of opportunity for successful implementation.

As a manufacturer, your challenge is to navigate the complex details of MDR and attempt to comply with the new requirements.

This checklist can provide you with insight into where you stand in regards to MDR preparation and what you still need to address.

Alira Health is here to help you manage the transition to MDR. This is a complex situation, and many companies are feeling lost. As regulatory consultants, we can identify and prioritize the MDR requirements, build a strategy, and implement the scientific requirements.

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- ☐ **Establish that your product is a medical device according to the MDR definition**
  Before you do anything else, you must establish that you meet the criteria for a medical device; some products may not actually qualify under this legislative framework. Make sure to double-check this.

- ☐ **Understand the classification of your device under MDR and the applicable Rule**
  The MDR contains 22 rules for medical device classification, and describes four classes: class I, class IIa, class IIb, and class III. You will need to justify in front of the notified body and which specific rule applies to the applicable device classification.

- ☐ **Specify the intended use, the target population, intended users and the applicable device classification**
  You must specify all of these items; these details can impact your device classification and categorization, as well as your clinical approach and the endpoints you will measure.

- ☐ **To benefit from the transition period, you must implement all the requirements as per Article 120**
  To benefit from the extended transition period to MDR, you must implement certain requirements. Otherwise, you will have to be ready by May 2024. Please make sure you comply with all the applicable requirements.

- ☐ **Have an existing relationship with a notified body or be in the process of establishing one**
  If you don't already have a relationship with a notified body, you need to start that process as soon as possible. This is a complex and lengthy process and delays can be expected.

- ☐ **Comply with the General Safety and Performance Requirements (GSPR) in the MDR**
  The GSPRs are defined in Annex I of the MDR and many have changed from the MDD. You need to demonstrate compliance with the GSPRs that are applicable to your product and describe the specific methods to demonstrate compliance with them.

- ☐ **Identify and comply with the applicable guidelines for your product, find out if any of them have changed, and describe the specific methods to demonstrate compliance with them**
  You must also still comply with other applicable standards and guidelines, and you should find out if a new version of such standards has been published and if it includes new requirements. If so, you need to analyse the gaps between the old and new requirements and understand what you need to do to be fully compliant.

- ☐ **Draft a plan for conducting the applicable testing as per the guidelines identified**
  Once you identify the guidelines with which you need to comply, and you've read them to understand how they apply to your device, you need a plan to execute the necessary testing.

- ☐ **Assess whether sufficient clinical evidence is in place for your device**
  This is important not only for new devices, but also for products that are transitioning from MDD to MDR. If you don't have sufficient clinical evidence, you need to execute a clinical investigation.

- ☐ **If clinical evidence needs to be generated, properly design and execute a clinical investigation**
  You need to understand what evidence you need to generate and design the clinical trial with the appropriate endpoints so that the results meet the MDR requirements.

- ☐ **Determine your Economic Operators and the Person Responsible for Regulatory Compliance (PRRC)**
  You must also contractually meet the MDR requirements. Also, you will need to appoint a PRRC with your Economic Operators. The MDR describes the specific qualifications the PRRC must have.

- ☐ **Implement or update your Quality Management System (QMS) to incorporate MDR requirements**
  If your product is new, you'll have to establish and work under a QMS, and if you have an existing product, you'll need to update your QMS to incorporate the new MDR requirements.

- ☐ **Design your post-market surveillance system, including the PMCF Plan and Study**
  You need to present a plan to the notified body that includes a Post Market Surveillance system and a Post Market Clinical Follow up (PMCF) Plan and Study. You must outline how you will monitor and confirm the safety and performance of the device once your product is on the market.

- ☐ **Comply with Annex II of the MDR which defines the technical documentation you must provide to the notified body**
  In order to make the submission to the notified body, you need to prepare a dossier that complies with specific requirements set up in Annex II of the MDR. You must follow the structure as it is defined.