

Understanding What Constitutes “Significant Changes” in Design and Intended Purpose of Medical Devices in the EU

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The MDR provides manufacturers with several transitional periods, effectively postponing obligations to comply with most MDR requirements for several years. As a result, medical devices that have a valid certificate issued by a Notified Body under the EU Medical Devices Directive (**MDD**) or the EU Active Implantable Medical Devices Directive (**AIMDD**) may continue to be placed on the EU market after the date of application of the MDR on May 26, 2020. Moreover, as recently reported in Sidley’s Updates (available [here](#) and [here](#)), the EU legislator has in a second corrigendum to the MDR (**Corrigendum No. 2**) added a four-year transition period for certain medical devices, including certain medical devices software, that are now classified as Class I but would be moved into a higher-risk class under the MDR.

To benefit from the transitional periods, medical devices must continue to comply with applicable MDD or AIMDD requirements after May 26, 2020. Importantly, there must be no significant changes in the design or intended purpose of those medical devices (MDR, Article 120(3)).

For manufacturers of medical devices that benefit from the transitional periods, it is critical to understand what constitutes a “significant change.” Any medical devices undergoing “significant changes” in their design or intended purpose must comply with all applicable MDR requirements, regardless of any potential time left in the applicable transitional period. For example:

- A medical device that has a certificate issued by a Notified Body in accordance with the MDD on July 7, 2019, and which is valid until July 7, 2023, will have to comply with the product-specific requirements of the MDR only after July 7, 2023. However, if the manufacturer makes a “significant change” to the device’s design or intended purpose, this upgraded medical device will have to comply with the MDR and therefore undergo the relevant MDR conformity assessment before it can be placed on the EU market.

MDCG Guidance

The MDCG is working on a draft guidance to help manufacturers and Notified Bodies assess whether changes or upgrades to their medical devices may constitute a “significant change.”

In the meantime, it may be helpful to stakeholders to consider existing guidelines to better understand how the concept of “significant change” could be defined in the future. The

Notified Body Operations Group (NBOG) issued a Best Practice Guide in 2014 (Guide, available [here](#)), which provides that product changes should be considered “substantial” (i.e., “significant”) if the change may affect

- a. the conformity with the essential requirements and/or
 - b. the indications, contraindications or warnings determined by the manufacturer to be appropriate to ensure the clinical performance of the medical device
- The Guide also provides a nonexhaustive list of considerations when determining whether a particular product change is “substantial” (e.g., changes of the materials), as well as examples of “substantial changes.” As an example, an alteration in software that modifies an algorithm affecting the diagnosis or the therapy delivered would be considered a “substantial change.” The Guide also covers “substantial changes” to the QMS.
 - Other international guidelines also consider changes other than to the “design and intended purpose” to fall within the scope of the term “significant changes.” For example, the June 2017 guidance issued by the International Accreditation Forum (IAF) (available [here](#)) addressing, *inter alia*, changes that could affect the decision on medical device’s state of compliance with regulatory requirements. According to the IAF, changes to the QMS may affect the design or intended purpose of medical devices (such as significant modifications to special processes, e.g., a change in the method of sterilization).

Based on NBOG and IAF’s positions, it is possible that certain changes to the QMS would also be considered a “significant change” within the meaning of Article 120(3) of the MDR.

- Most recently, in February 2019, four industry groups published a joint industry position paper on “Significant Changes According to MDR Article 120(3)” (Joint Industry Position, available [here](#)). The objective of these industry groups was to provide a harmonized interpretation and ensure a level playing field between Notified Bodies and manufacturers that may otherwise interpret the term “significant” inconsistently. Largely based on the Guide, the Joint Industry Position proposes that changes are classified into five categories:
 1. intended purpose
 2. design or performance specification
 3. ingredient or material
 4. sterilization or packaging design with impact on sterilization
 5. software

Software changes that should be considered “significant,” according to the Joint Industry Position, include new or major change of operating system, new or

modified architecture or database structure, change of an algorithm, new feature and new user interface that have an impact on the diagnosis or therapy delivered to the patient. Software changes that have no impact on the diagnosis or therapy delivered to the patient may include new nonmedical features, correction of an error that does not pose a safety risk, security updates (e.g., cybersecurity enhancements and longevity calculations), appearance of the user interface and operating efficiencies.

The guidelines mentioned above indicate that Notified Bodies should assess any change on a case-by-case basis. Manufacturers of medical devices benefiting from the transitional periods should note that Notified Bodies will be examining their medical devices through the lens of the MDR as of May 26, 2020. For gray zone changes, manufacturers may want to consult their Notified Bodies and discuss with them whether those changes would be considered “significant.”
