Whitepaper

News on the Postponement of the EU Medical Device Regulation, Corrigenda and MDCG guidance

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This paper focusses on the legislative developments surrounding the 2017 adopted EU regulation for Medical Devices (EU MDR). It addresses the postponement of the implementation date originally set for May 26th, 2020, the two corrigenda published and the available EU MDR guidance from the Medical Device Coordination Group (MDCG).

Upon reading this paper you will learn the reasons and consequences, including the benefits, of the EU MDR postponement, understand what has changed in the original published regulation based on the corrigenda, and what the main topics are that have received supportive guidance.

Background

The predecessors of the EU MDR are the EU Medical Device Directive (MDD) and the Active Implantable Medical Device (AIMD). These two directives, which will continue to be valid until the Date of Application of their successor, focus on requirements for manufacturers and agencies and less on those for notified bodies, importers and distributors.

The new EU MDR, combines both medical devices, active implantable devices and now also devices with no medical intent[1)] (but with a similar risk profile), the role of importers and distributors is made clearer as also the expectations on Notified Bodies cannot be overlooked.

The date of application of the In Vitro Diagnostics Medical Devices Regulation (EU IVDR) is not affected by the current postponement of the EU MDR and will become applicable from May 26th 2022, as planned.

EU MDR has been postponed with one year

The reason

The reason for the EU postponement was worded by Stella Kyriakides, the EU Commissioner for Health and Food Safety, as follows: *"to support Member States to address the coronavirus crisis and protect public health as powerfully as possible – by all means necessary."* The Commissioner pointed out that as the COVID-19 crisis increased demands for certain vital medical devices, any potential market disruptions regarding the availability of safe and essential medical devices must be avoided. Given the current pressure on national health authorities and manufacturers of medical devices, there is a fear that there could be shortages or delays in getting the medical devices needed to fight COVID-19, were they to follow the new rules of the Medical Devices Regulation from May this year. Therefore, the current rules will continue to apply for one more year.

The process followed

Whilst getting closer to the MDR date of application (DoA), and understanding the urgency for device companies to focus on current product availability rather than MDR compliance, the

[1] *Guidance on product without a medical intent (MDR Annex XVI products)* https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/748131/Guidance_leaflet_on_Annex_XVI_products_.pdf

European Commission[2]) planned, prepared and proposed a new European law to postpone its application date. The Commission, upon being convinced that the postponement law would serve the interest of the Union and its citizens submitted a legislative proposal to the European Parliament and the Council of the European Union. Given the urgency and support by all, they both agreed on the text of this new EU law. The European Parliament adopted the Commission's proposal with 693 votes to one (2 abstentions) on April 17th. So, within a few weeks the proposal was drafted, submitted, approved and is now officially published in the Official Journal as "*REGULATION (EU) 2020/561 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices*"[3]).

An unofficial consolidated version of the MDR, including the new amendment and two previous corrigenda is available in EUR-Lex[4]).

Consequences of the EU MDR postponement

The main changes

The rules of the EU MDR are postponed with one year and will now be enforceable as of May 26th, 2021. This date is also referred to as the Date of Entry into Force or the Date of Application (DoA).

Manufacturers will have now more time to tackle the difficult and new topics addressed in the EU MDR, such as: labeling requirements; understanding the EUDAMED, gathering available post-

[2] *What the European Commission does in law* https://ec.europa.eu/info/about-european-commission/what-european-commission-does/law_en

[3] *REGULATION (EU) 2020/561* https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32020R0561

[4] Consolidated MDR EUR-Lex version https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1591042433647&uri=CELEX:02017R0745-20200424

market safety and performance data to incorporate in clinical evaluations under MDR; technical documentation updates; and implement the newly published MDR guidance of the Medical Devices Coordination Group (MDCG). Automatically, for some companies this means that the MDR compliance projects are extended in time and may as such become more costly and occupy resources for a longer time.

Notified Bodies may continue to assess products under the Medical Device Directives for one year longer, meaning that some products may stay now longer on the market.

Notified Bodies have gained more time to assess products for MDR compliance while the previous Medical Device Directive (MDD) remains also still effective. Notified Bodies could therefor also still provide for MDD re-certification certificates with validity beyond the date of May 26th of 2021, in theory. However, such effort is much dependent on each Notified Body's business and resource strategy. Most likely many NoBo's were already focused on MDR only and will not again advocate or take on new work for MDD compliance. It is likely that resources were already shifted towards de MDR and also at current there will be practical internal limitations on resource availability due to COVID-19 and also due to travel restrictions and restriction to visit manufacturing sites.

The extra time will help some Notified Bodies to finally become designated to the MDR. At current still there are only 14 Notified Bodies designated of which 5 in Germany and 3 in the Netherlands.

Compliance to Common Specification (CS) follows the DoA of the MDR. No CS have been published yet but are expected to be published over the course of this and next year. CS intent to provide additional requirements for specific products or activities. They may address general safety and performance requirements, technical documentation, and clinical evaluation or performance topics. When published, the CS shall apply as from six months after the date of entry into force of such CS, but in no case before May 26th of 2021.

What does not change

The dates on MDD (re-)certification certificates do not change. The much-sought re-certifications of products under MDD to extend the certificate validity beyond the DoA of the MDR has now become less effective as the end dates of those certificates do not move with the delay of the MDR. Also, the maximum grace period of MDD certificates is not extended, meaning that the expiry date of MDD certificates remains May 26th, 2024.

The effort required to become MDR compliant has also not changed. One could even say that the effort has become more complex due to additional guidance being published. In the last two months alone, 19 new guidance documents were issued. Also, there may be relevant CS or updated international standards being published from IEC or ISO (e.g. ISO 14971). Furthermore, due to COVID-19, Notified Bodies may not have the ability or limited ability to assess your products, quality system and audit your facilities due to travel restrictions and limited resources. Notably, the new MDCG guidance on remote audits (to facilitate the COVID-19 situation) does not apply to MDR and it does not apply to new assessment applications in any event.

The date of the introduction of EUDAMED remains the same. Deployment of a fully functional EUDAMED is still intended for 2022. According to the Rolling plan - updated in May 2020 -, EUDAMED may go-live from the moment a notice is published in the Official Journal of the European Union after a positive independent audit is performed by the MDCG. The planning for the audit date is not known yet, but could be end of 2021 or early 2022.

The situation on standards has not changed. The extra year, due to the postponement of the MDR, will hopefully provide clarity on the status of Standards in regards to them being harmonized for the MDR. The best advise now for manufactures is to assure that each selected relevant standard is justified based on State-of-the-Art considerations for the applicable product or process.

The content of the EU MDR Corrigenda

Two MDR corrigenda were published, one in March 2019 and one in December 2019. The corrigenda corrected mainly faults or addressed topics that seems overlooked in the first MDR version. From that perspective the corrigenda do not have a relationship with the current amendment, nevertheless it is good to know what was corrected in those two corrections.

Corrigendum 1

Corrigendum 1[5] included 14 corrections of which some minor textual, date or editorial changes. One change meant that products of animal origin that were legally placed on the market prior to 26 May 2021 (first 2020) will not be allowed on the market after that transition date in such member states that previously allowed them. Some corrections broadened the applicability of requirements, i.e. Annex IX on QMS based conformity assessments was corrected from “Surveillance assessment applicable to class IIa, class IIb and class III devices” to just “Surveillance assessment.” Another correction broadens what device accessories will be classified, changing a line in Annex VII, Section 3.2 that reads: "… Accessories for a medical device and for a product listed in Annex XVI shall be classified in their own right …", to: "… Accessories for a medical device shall be classified in their own right … ".

Corrigendum 2

This corrigendum[6] was more relevant for a broader group of manufacturers, i.e. those which products would require a (new) Notified Body certification under MDR. Also, under the MDR,

[5] MDR corrigendum 1; https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32017R0745R(01)

[6] MDR corrigendum 2; https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32017R0745R(01) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32017R0745R(02)

originally there was no transition period for class I devices. The key issue in the second corrigendum is therefore the introduction of a transitional period for those devices that are classified higher under the MDR than they were under the Medical Devices Directive (MDD) and therefore require the involvement of a notified body. An example is reusable surgical instruments (Class Ir) that, under the MDR, require a notified body to assess the aspects related to the reuse of the instruments. Another example is medical device software; most of these software products will be up-classified from Class I to Class IIa under MDR and therefore will also require involvement of a Notified Body. This category can also make use of the transition period. Last example would be many self-certified substance-based devices, of which some would be up-classified as far as Class III. Notably, with the MDR postponement now, the start of this transition period is now set to May 26th of 2021, but the end date remains May 26th 2024. The transition period is consequentially shortened from 4 to 3 years.

Be aware, despite the delay on the certification requirement, still there is no delay in application of the MDR itself for those manufacturers and products. Manufacturers must still set up quality management systems, procedures for risk management, clinical evaluation procedures and PMS/PMCF procedures, and maintain these procedures. Manufactures however are able to make good use of the delayed certification by the notified body since they have now more time to meet the more stringent requirements for clinical data. In the meantime real-life data can be obtained from its market use and will facilitate building routine in drafting clinical evaluation plans, PMS and PMCF plans and subsequent reports (e.g. PSURS), even if not all these reports are required yet.

Note further, this delay can only be used if there are no significant changes made in the design and the intended use of a device after May 2021. The changes will not be monitored by a Notified Body

if there is no current MDD certificate and it is not clear if and how Competent Authorities plan to monitor this situation.

News on MDCG Guidance

Since the MDR was published in 2017, the European Commission provides a range of guidance documents[7] to assist stakeholders in implementing the medical devices regulations. Legally they are non-binding guidance documents, adopted by the medical device coordination group (MDCG) in accordance with Article 105 of Regulation 745/2017, with the intent to ensure uniform application of the relevant provisions of the regulations within the EU.

Main topics addressed in the Guidance documents are:

- UDI (Unique Device Identification)

  Already 9 guidance documents exist in an effort to introduce both unique device manufacturing data as also product characteristics in one new item that is new to the EU, but is in a similar form already in place in other regions (e.g. US). The UDI is displayed on the product labeling, is also used in the processes of keeping products traceable over the life-cycle of the product by different economic operators (e.g. manufacturer, importer and distributor) and is also relevant in the EUDAMED database. Note that the main guidance on this topic, i.e. MDCG 2018-1 **v3**, titled "Guidance on basic UDI-DI and changes to UDI-DI", has already its third revision published.

[7] MDCG guidance portal; https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en

- EUDAMED and EMDN

  Guidance is available that provides an explanation on when, how and by whom products will need to be registered in the central EU Database for medical devices. Also, this system will make use of new nomenclatures for devices, called the European Nomenclature on Medical Devices (EMDN). The EMDN will overhaul the GMDN coding and is based on the Italian "Classificazione Nazionale Dispositivi medici" (CND)[8] .

- Notified Body Guidance

  Guidance that helps Notified Bodies to interpret and guide the ways they need to understand, and execute the MDR. Topics are relevant in first instance for the Notified Bodies themselves, however also manufacturers can learn in which way the MDR requirements will be verified by these assessing parties. The MDCG guidance directed towards Notified Bodies is for manufacturers interesting particularly if they manufacture combination products with drugs, or if products have an animal origin, if products are relevant in battling the COVID-19 pandemic, or if products have MDD certificates or need significant changes or want to transition to MDR. Most of them provide interesting reads for multiple stakeholders.

- Guidance on Clinical investigation and evaluation

  Not surprisingly much guidance is dedicated to the clinical aspect of medical device products. It was one of the reasons for the MDR update in 2017 to focus more on clinical safety and clinical performance and also to monitor this over the whole life-cycle of the

[8] Italian CDN coding; **Error! Hyperlink reference not valid.**http://www.salute.gov.it/

device. Guidance is relevant and even provides a Summary safety report form as an appendix guideline, i.e. MDCG 2020-10/2.

- Other topics

  There is more guidance and this is mostly on topics that were impacted heavily from the MDD to MDR transition. Such topics are: Class I products, the role of the Person Responsible for Regulatory Compliance (PRRC) and medical device software.

The MDCG guidance portal provides also a listing of upcoming guidance. If you do not want to get surprised, make sure to check the upcoming subjects there.

The EU MDR postponement in summary

The MDR is postponed due to the COVID-19 crisis, but it is clear one should not lean back now. Still there is so much to do; new guidance is published by MDCG every month, with COVID-19 your planning may have become unreliable and work in progress less effective. Next year is already round the corner and one cannot conclude otherwise: the MDR date of application is inevitable and compliance must be your continuous driver for the months to come.

About Starodub

Reliable, Efficient and Knowledgeable

Starodub BV was founded in May 2014. The company started with one employee, the founder Valentyna Starodub. By today, our team has grown to round 20 employees and has a valuable network of specialized experts. We partner with (bio)pharmaceutical and medical device companies worldwide to ensure that regulatory requirements are met and business goals, such as quick market access and compliance, are achieved. Please check the Our services page to learn how we can support you with meeting your business goals.

Our lean and powerful team strives to be of added value to our clients. All employees are highly educated and obtained degrees in pharmacy, chemistry, biology or related. Our short reporting lines are key to finding the most efficient road to your success. One of our experts will be your primary contact and the team's collective knowledge and resources are available to give reliable advice and execute projects in the most efficient way. Together, we connect the dots and look beyond the scope of projects to make sure all aspects of importance are addressed.

At Starodub BV consistency and assurance of quality are considered as being highly important. A quality management system has been implemented and we strive to comply with GxP and ISO 9001/13485 constantly. In addition, we have an external board of control, acting as the sparring partner to set the optimal course for our company.

We strive to be a true partner to Our clients, who rate our services as ≥4.5 on a scale of 1 (poor) to 5 (excellent). This motivates us to maintain the highest professional standards and to implement continuous improvement.

About the Author

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Erwin Waas is a former Senior RA Manager of Starodub BV (2014-2020). He is an expert on medical devices. In case you would like to ask a question on this white paper, please contact Valentyna Starodub at info@starodub.nl