



MDR COMPLIANCE POSTPONED UNTIL MAY 2021 WHAT YOU CAN DO NOW

As published in the *Official Journal of the European Union* on 24 April 2020, the date of application of Regulation (EU) 2017/745 on medical devices (MDR) was postponed to 26 May 2021. Due to this decision, several timelines have been extended for one year which directly affects every manufacturer on the market. We cover what is changing and what remains the same with the MDR, as well as other areas impacted by the date change.

INTRODUCTION

Since the beginning of 2020 the COVID-19 pandemic slowed most of the economy in the European Union. This resulted in many different challenges ranging from notified bodies that were no longer able to perform audits, to manufacturers that were forced to increase their production beyond their existing capabilities or forced to stop their production all together.

To tackle these problems, the European Commission made the proposal to defer the date of application of the medical device regulation by one year to “ensure the smooth functioning of the internal market, a high level of protection of public health and patient safety, to provide legal certainty, and to avoid potential market disruption.”

This proposal only applies to Regulation (EU) 2017/745 on medical devices and NOT to Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices.

RELEVANT CHANGES

In general, almost all instances of the date 26 May 2020 in the MDR were changed to 26 May 2021. This means that devices that are currently compliant with the European Council Directives 93/42/EEC on medical devices (MDD) and 90/385/EEC on active implantable medical devices (AIMDD) can be placed onto the market for one more year. This is especially relevant for



manufacturers of Class I medical devices since they will have another year to prepare for the MDR. The one-year extension also benefits Class I devices that are being up-classified due to the MDR's new classification rules, as well as devices of higher classes. The overall transition time of seven years starting on 26 May 2017 does not change, but it means one less year for discussions and potential problems with the significant change issue (article 120 (3)) and one additional year in which the stricter PMS requirements of the MDR do not yet apply. Furthermore, manufacturers have one more year to prepare the submission package and apply for their new MDR certificates through their notified bodies.

For notified bodies, this will result in more time to issue MDR compliant certificates. As for the European Commission and the competent authorities, there is now more time to designate more notified bodies as well.



In theory, notified bodies may now certify or recertify devices until 26 May 2021 under MDD/AIMDD. How much this option will be used remains to be seen. Notified bodies already designated under the MDR have changed their processes and relocated their resources to the demands of the regulation as much as possible. Notified bodies that have not yet applied to work under the MDR may not have the resources to pursue designation. Therefore, it is very likely that the best chance of obtaining a new certificate between now and May 2021 is to pursue an MDR certificate.

DEROGATION FROM THE CONFORMITY ASSESSMENT

Some major changes were made regarding article 59, derogation from the conformity assessment procedures. This article allows competent authorities of all Member States to place specific devices on the market that are not fully compliant with the MDR but whose use is in the interest of public health or patient safety or health. Furthermore, the EU Commission is now able to extend national exemptions via article 59 to the whole EU territory. This gives competent authorities and the EU Commission more freedom to get products on the market more quickly in response public health threats, including the COVID-19 pandemic.

EUDAMED TIMELINE

Based on the shifted timeline for the MDR, the launch date for the possible notice-of-function European database on medical devices (EUDAMED) according to article 34 was changed to 2021 as well. This does not have an immediate impact, but manufacturers need to monitor this topic closely to be sure they are ready by 26 May 2021. However, it is still likely that the release date for EUDAMED will remain 2022.

NATIONAL LAWS

All Member States are required to change their national laws to fit the new MDR. Some of the states already prepared or enacted the required laws, but in line with the MDR, the effective date will need to be changed to 26 May 2021.

INDIRECT CHANGES

With the MDR delay the mutual recognition agreements with Switzerland and Turkey remain valid and thus these countries are still considered as part of the European market under the existing directives MDD and AIMDD. This gives both countries a longer time to negotiate an agreement with the EU.

The Brexit situation is a bit more complicated. Based on the current status the UK will no longer apply EU laws by end of December 2020. For manufacturers inside the UK this means they must comply with the MDD/AIMDD until December. Afterward, they must apply their national law as long as no changes in the Brexit situation occurs.

THINGS THAT DID NOT CHANGE

As relevant as the described changes are, many other things did not change due to this decision. A major example is the transitional provisions in article 120 (2). These retain the original dates and MDD certificates will become void as they expire, but no later than 27 May 2024.

The same applies to former Class I devices that will now need certification through a notified body. Their transition period will still end in 2024.

The transition periods for the UDI on a device label from articles 123(f) and (g) are not affected either. The UDI carrier will have to be part of the device label by 2023 for Class IIa and IIb devices and by 2025 for Class I devices. For Class III devices and for implantable devices, this requirement will apply from the new date of application.

OUR RECOMMENDATIONS

This additional year brings a lot of opportunities to all manufacturers. But it should not be taken lightly. Simply extending MDR project milestones that were originally scheduled for completion in May 2020 to May 2021 would not be a wise choice. We strongly recommend keeping up the pace and being finished ahead of time. This will grant you more time to focus



on upcoming challenges, such as finding a notified body or stress-testing your new procedures in a live environment. This will give you a market advantage and help assure a better product with more flexibility to react.

If you have already placed your Class III or implantable devices on the market with a valid MDD certificate and want to make use of the clause in Article 61(6a) regarding exemption from clinical investigations, use the additional time to conduct PMCF studies and gather clinical data with your own devices. The recently released guidance MDCG 2020-6: *Clinical evidence*

needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC suggests that “sufficient clinical data” for these devices may only be assumed if the clinical evaluation contains premarket clinical data with high clinical evidence and is verified by post-market clinical data from PMCF studies. It must be noted that reliance solely on factors such as long market presence, well-established technology or vigilance data will not be sufficient.

In addition, it is important to monitor the national law as well as the EUDAMED implementation schedule, since these will affect your work in the foreseeable future.

YOUR NEXT STEPS

- > Update your regulatory strategies and policies
- > Reschedule your MDR transition, quality and training plans
- > Review all new common specifications, MDCG guidelines and standards
- > Reconsider your portfolio for products that can benefit from the MDR delay
- > Contact your notified body to confirm a new MDR schedule
- > Plan to implement changes that could be considered “substantial” under Article 120 (3)
- > Close MDR remediation work as soon as possible
- > Check for freed-up MDR resources and allocate them to your project planning
- > Stay in close contact with UK, Turkish and Swiss distributors for upcoming changes

The extension of the MDR date of application allows the industry to take a deep breath, but this time should not be wasted. We are here to help you with all the upcoming challenges and continue to work together to ensure efficient ways of being in compliance with the MDR.

For more information, contact info-medicaldevices@nsf.org

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Cite as: NSF International. April 2020. MDR Compliance Postponed Until May 2021: What You Can Do Now. NSF: York, UK.

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LMD-809-0420