The Impact of COVID-19 on the Medical Device Regulation (MDR)

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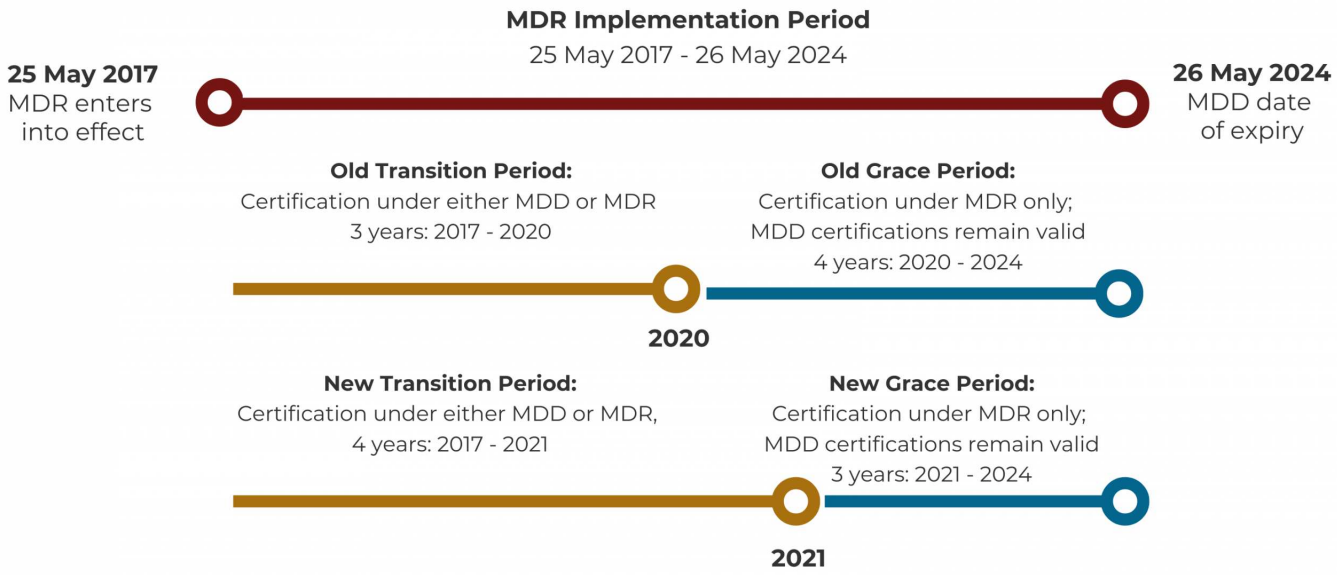
What is the Rationale for the Delay?

On 23 April, 2020, a unanimous 27-0 vote by the European Council ushered in an amendment to delay implementation of the Medical Device Regulation (MDR) by 1 year, to 26 May, 2021. This delay is intended to empower member states to divert resources towards fighting COVID-19, supporting their citizens, and rebuilding in what will undoubtedly be an altered economic and geopolitical landscape. For device manufacturers, this delay will allow for continued utilization of the Medical Device Directive (MDD) and additional time to demonstrate sufficient clinical evidence in support of their products' safety and performance.

As with all areas of society, the medical device industry has been greatly impacted by COVID-19. Social distancing measures, patient hesitance to enter medical facilities, and efforts to conserve personal protective equipment (PPE) have resulted in a sharp decrease in elective surgeries, routine medical procedures, and participation in clinical trials. Interest groups have argued that a delay is needed to allow device manufacturers to devote resources to helping fight the pandemic and to prevent interruptions in medical device supplies resulting from difficulties in obtaining MDR certification. Continuity of supply is especially relevant to medical devices needed to treat COVID-19, such as ventilators, rapid testing kits, and PPE.

What is Affected by the Yearlong Delay?



Key Takeaways

Delayed MDR Date of Application ≠ More Time for MDR Implementation

- The delay extends the transition period in which medical devices can be certified under MDD or MDR by 1 year, from May 2020 to May 2021.
- Devices with an MDD date of expiry after May 2021 will still have to be submitted under MDR.
- Per Medical Device Coordination Group (MDCG) guidance, there may be possible delays of on-site audits and/or potential remote audit options.
- Notified Bodies have 1 additional year to become MDR certified.

What Remains Unchanged?

MDR Documentation Update Requirements Have Not Changed

Device Class	Risk Level	Examples	Requires Notified Body Approval?	PSUR Update Frequency*	SSCP Update Frequency**µ	PMSRs Update Frequency*** µ
Class (III) AMID	High	Implantable Pacemaker, Left-Ventricular Assist Device	✓	At Least Annually	At Least Annually	NA
Class III	High	Endocardial Occluders, Drug-Eluting Stents	✓	At Least Annually	At Least Annually	NA
Class IIb	Medium-High	Ventilators, Orthopedic Implants	✓	At Least Annually	At Least Annually (Only For Class IIb Implantables)	NA
Class IIa	Medium-Low	Hypodermic Needles, Hearing Aids	✓	When Necessary And At Least Every 2 Years	NA	NA
Class I	Low	Non-Medicated Sterile Dressings, ECG Patches	✓	NA	NA	When Necessary
Class I (Measuring)	Low	Volumetric Urine Bag	✓	NA	NA	When Necessary
Class I (Reusable) Basic	Low	Reusable Surgical Instruments	✓	NA	NA	When Necessary

While the extra time can be helpful, it is important to remember that none of the new requirements under MDR have changed.

- There has been no change to last date to sell warehouse inventory placed on the market before expiry of MDD certification.
- The previous dates for Unique Device Identifier (UDI) and In-Vitro Diagnostic Regulation (IVDR) remain unchanged.
- The date of expiry for currently issued MDD certificates is unaltered.
- EUDAMED launch date of May 2022 remains unchanged.

* EU MDR 2017/745, Article 86
** EU MDR 2017/745, Article 32
EU MDR 2017/745, Article 61
*** EU MDR 2017/745, Article 85

What Does the Delay Mean for Medical Device Companies?

Greater number of Notified Bodies (NBs) with MDR designation

As of 21 September, 2020, there are 17 NBs designated under MDR, including 3EC International a.s., BSI Assurance UK Ltd, BSI Group The Netherlands B.V., CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft., DARE!! Services B.V., DEKRA Certification B.V., DEKRA Certification GmbH, DNV GL Presafe AS, DQS Medizinprodukte GmbH, GMED, IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A., Intertek Medical Notified Body AB, MDC MEDICAL DEVICE CERTIFICATION GMBH, MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH, National Standards Authority of Ireland (NSAI), TÜV Rheinland LGA Products GmbH, TÜV SÜD Product Service GmbH Zertifizierstellen.[1]

Need to confirm with NB how long they will accept MDD applications

We advise that companies continue pursuing MDR instead of re-certifying under MDD. If you feel like you are not prepared for MDR, but the Clinical Evaluation Report (CER) is nearing completion, we have created CERs that can be used for MDD then quickly resubmitted for MDR, as well as CERs that enable MDR and MDD certification simultaneously.

Potential audit delays

Medical Device Coordination Group (MDCG) issued guidance addressing the possibility of delaying on-site audits and potentially replacing them with remote options. Virtual audits would be dependent on the NB and medical device company assuring that information and data would be transmitted securely.[2,3]

Publication of more guidance documents to support manufacturers

In addition to the MDCG's guidance regarding on-site audits, several additional publications on clinical investigation and evaluation have been shared with the public.[3]

- Guidance on safety reporting in clinical investigations Appendix: Clinical investigation summary safety report form (MDCG 2020-10/1, MDCG 2020-10/2)
- Guidance on PMCF evaluation report template (MDCG 2020-8)
- Guidance on PMCF plan template (MDCG 2020-7)
- Guidance on sufficient clinical evidence for legacy devices (MDCG 2020-6)
- Guidance on clinical evaluation – Equivalence (MDCG 2020-5)
- Summary of safety and clinical performance (MDCG 2019-9)

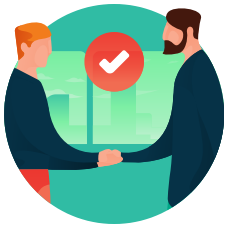
MDR Preparedness Trends in the Medical Device Industry

Data indicate that most medical device companies will need the extra time in order to become MDR compliant. In 2018, KPMG and the Regulator Affairs Professional Society (RAPS) conducted a survey of 220 medical device companies to understand their progress towards MDR compliance. They found that:

78% believe they do not have a strong understanding of all the new MDR requirements

58% report not having an established strategy to address gaps in their clinical data

41% report that they do not have a long-term plan in place for MDR compliance



39% report that they have not identified an individual to act as the Person Responsible for Regulatory Compliance (PRRC), nor have they defined and documented this individual's roles and responsibilities

This is Not a Time to Pause.

MDR is an inexorable part of the medical device industry's future.
In addition to focusing efforts on fighting COVID-19, this time should be used to earnestly prepare for the new May 2021 MDR deadline. The delay provides critical time to collect more data and develop MDR-compliant source documents. One can assume the bar for preparation will be higher due to the 12 additional months industry has to prepare. With these standards in mind, it is more critical than ever to strategically assess remediation plans and quickly make any necessary changes.



How Can Medical Device Companies Make the Most of this Time?

- Perform a cost/benefit analysis for each device to identify those well-suited for remediation
- Identify gaps in clinical evidence
- Determine measurable safety and performance criteria
- Plan and initiate Post-Market Clinical Follow-Up (PMCF) studies
- Determine risk class
- Get a Quality Management System (QMS) in line
- Finalize Instructions for Use (IFU) and risk documents
- Get contracts in place with third-party vendors
- Establish a relationship with an MDR-certified Notified Body

Authors

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Jessie is an epidemiologist turned medical writer with therapeutic specialties in structural heart, vector borne/zoonotic disease, and children's environmental health. She loves tailoring her writing to suit the readers' needs, whether they be regulatory authorities, patients, healthcare professionals, or people for whom English is a second language. Some of her professional accomplishments include creating a product theater presentation delivered at the annual meeting of the American Psychiatric Association, publishing in the journal Zoonoses and Public Health, contributing to research published in the CDC's Emerging Infectious Diseases, and volunteering as a health educator in Nepal.

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