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The Effect and Impact of the MDR Delay- Controversies Continued

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This presentation is based on information available as of today and prepared to my best knowledge as subject matter expert. This presentation presents my personal understanding of the medical device requirements in Europe and is not reflecting the view of TÜV SÜD PS.

Summary

- Content amending Regulation 2023\607
  - Timelines & conditions
  - Scope
- Ongoing work on implementation issues
  - EU COM
  - Notified Bodies

Conditions for extra time in amending Regulation 2023/607

- Underlying legislators' 'dilemma' for amending Regulation:
  How to give extra time to legacy devices to transition from MDD/AIMDD to MDR
  - when MDD and AIMDD are repealed (by MDR art 122)?
  - when MDD/AIMDD certificates are expired?
  - when you want to encourage manufacturers to go to MDR?

- Solution chosen:
  - extra time is granted to transition to MDR after expiry of the MDD/AIMDD certificate
  - only if manufacturer shows evidence of progress with MDR transition
  - extra time is based on expired certificate PLUS fulfilment of conditions

- What are the conditions?
  - MDR application lodged with an MDR notified body before 26 May 2024
  - Contract between the manufacturer and MDR notified body signed before 26 September 2024
  - Requirements for legacy devices in existing MDR art 120.3 are met, i.e.
    i. No significant changes
    ii. Vigilance and other post-market requirements according to MDR

Amending Regulation 2023/607: new MDR-timelines

Deadline transition date	Note: classification in amending Regulation = MDR classification
26 May 2026	Class III custom-made implantable devices
31 December 2027	Higher risk devices: class III devices and class IIb implantable devices*, *except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors
31 December 2028	Medium and lower risk devices: other class IIb devices and class IIa, class Im, Is and Ir devices
26 May 2021 no change	*Class I devices (other than Im, Is, Ir)*

Scope of the amending Regulation 2023/607

- Only ‘legacy devices’ can benefit from the extended transitional period.

- In line with MDCG 2021-25 ‘legacy devices’ should be understood as devices, which, in accordance with Article 120(3) of the MDR’s transitional provisions, are placed on the market after the MDR’s date of application (DoA) and until 26 May 2024 if certain conditions are fulfilled. Those devices can be:

  – devices which are class I devices under Directive 93/42/EEC (MDD), for which an EC declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure under the MDR requires the involvement of a notified body;

  – devices covered by a valid EC certificate issued in accordance with Directive 90/385/EEC (AIMDD) or the MDD prior to 26 May 2021.

Provisions for certificates expired before date of entry into force of amending Regulation 2023/607

- Certificates that have expired before the entry into force of the amending Regulation (20 March 2023) shall only be considered valid if

  – either before the date of expiry of the certificate, the manufacturer and a notified body have signed a written agreement for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device,

  – or a national competent authority has granted a derogation in accordance with Article 59(1) MDR or has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure within a specified period of time

New element in amending Regulation 2023/607: ‘device intended to substitute a legacy device’

- Explanatory memorandum, Section 5
  “ The extension should, however, also apply to ‘legacy devices’ that the manufacturer intends to replace by a ‘new’ device for which it applies for conformity assessment before 26 May 2024. In this way, unnecessary applications for certification of devices that will in any case be phased out and replaced by a new generation of devices will be avoided, whist keeping the existing models available until the end of the transition period.”

Work on practical implementation: EU COM Q&A Document

- Official title:
  Q&A on practical aspects related to the implementation of Regulation 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices
- Workshop with all stakeholders on 13 March 2023
- Useful document
- Published 27 March 2023, see Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 - Extension of the MDR transitional period and removal of the "sell off" periods (europa.eu)

- MDCG meeting 17 April 2023 in Brussels
  - EU COM announced **update** of Q&A Document
    i. Stakeholders (industry associations, notified bodies & others) can send Q plus draft answers to EU COM
    ii. workshop with stakeholders in similar set-up
- EU COM announced further work on alignment of MDR extension:
  - With Annex XVI Common Specifications (Regulation 2022/2346)
  - With several relevant MDCG guidances (2020-3 on significant change; 2022-04 on appropriate surveillance and 2021-25 on legacy devices)

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Work on practical implementation: Notified bodies

Team-NB *ad hoc* Taskforces working on important deliverables

- confirmation letter for lodged MDR application and signed contract
- ‘points to consider’ for contracts between notified bodies and manufacturers
- ‘tripartite agreement’ in case ‘MDD/AIMDD notified body’ and ‘MDR notified body’ are not the same
  - Amending Regulation 2023/607 stipulates that ‘MDR notified body’ needs to take over appropriate surveillance at the latest 26 September 2024

The new MDR timelines „cookbook“

- Continue ongoing projects!
- Apply as early as possible!
- Lock-in start time for MDR assessment
- Line-up your resources