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Provisions of Certified Products and Renewal of Certifications

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General information

- **The MDR requires a new evaluation of conformity of each product to be sold under the MDR rules**

- **Some transition rules implemented**
  See Internet-Page of the BMG, Nationaler Arbeitskreis FAQ

  https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/N/NAKI/NAKI_02-05_UG1_MDR_FAQ_UEbergang.pdf

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General information

- MDR was issued May 5th, 2017 and set valid May 27th, 2017 / 3 years transition period
  - Articles 120 to 123 contain rules for transition period and application rules
- MDR is mandatory by May 25th, 2020
- MDD becomes invalid May 26th, 2020
- EG-Certificates issued during the transition period could stay valid by May 27th, 2024
- Products can be sold by sales agents (not by manufacturer) when the products taken into service by end users by May 26th, 2025)

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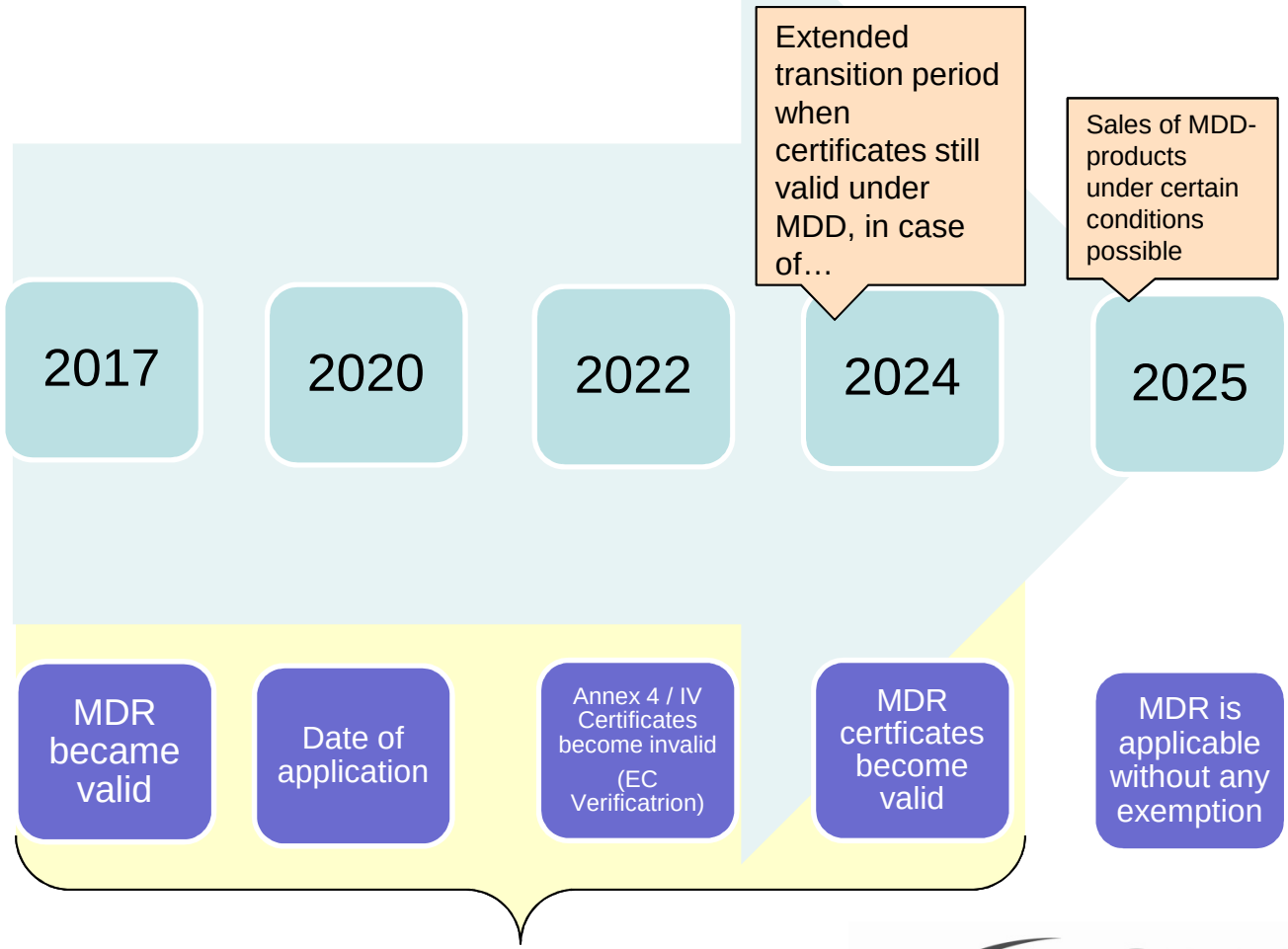
Overview: Time Lines for Implementation



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General Information about Compliance of Medical Devices within the EU

- **General rules for current and new regulation :**
  - **For Medical Devices the Legal Manufacturer has to declare the conformity in his own and sole responsibility**
  - **Declaration of Conformity (DoC) based on two parts mainly (Depends on the chosen moduls from MDR)**
    1. Product safety and effectivness (Technical Dossier/ EG-Certificate) and
    2. the guarantee of fullfilment of the applicable quality system (Quality management in accordance to ISO 13485 and additional requirements, see TR 17223:2018)

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General Information about Compliance of Medical devices within the EU

- CE-Dossier/ Technical Documentation: Evidence of Safety and Effectivness of the MD ⇒ Required for all products
- EG-Certificate : Issued based on the reviewed CE-Dossier/ Technical Documentation. It confirmes the Product Compliance reviewed by Notified Body (NB) ⇒ required for Products in Class I^s, I^r, I^m, IIa, IIb and III
- ISO 13485-Certificate: Certification of the organisation of the Legal Manufacturer by NB
- Additional requirements for the manufacturer´s organisation, like Medical Device Vigilance system, UDI, Incident Reporting etc.

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CE-Dossier / Technical Documentation / EG-Certificates

- CE-Dossier / Technical Documentation have to be in compliance with the requirements of MDR by Date of Application (DoA) May 25th, 2020 (Products under MDR- Requirements) when sold as MDR compliant (for Class I devices mandatory)

  Please refer to
  http://www.imdrf.org/docs/imdrf/final/procedural/imdrf-proc-150708-toc-pilot-plan-02.pdf
- EG-Certificates based on MDR- CE-Dossier / Technical Documentation can be issued by the DoA of the MDR or earlier if all required conditions are given
- Based on Artikel 120 MDR the certificates can be issued earlier when all required conditions are given (e.g. consultation procedure in place)

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CE-Dossier / Technical Documentation / EG-Certificates

- EG-Certificates based on MDD- CE-Dossier / Technical Documentation can stay valid by May 27, 2024, but the conditions to stay with such certificate could be complexe:
  - If you have to switch over the EG-certificate from one NB to another, because current NB will not be accreditated for MDR
  - In case of significant (affecting safety and/or effectivness) changes to the products are required and conformity has to be assess again. The former basis for conformity assessment (MDD) is not valid anymore.

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Organisational Requirements / ISO 13485- Certificates

- ISO 13485:2016 will be mandatory in May 2019
  (Way to provide evidence about the fulfilment organisational requirements is to be certified in accordance to ISO 13485 as Legal Manufacturer of products of class IIa, IIb and III)

- The handling of the evidence proof of additional organisational requirements (in addition to ISO 13485) addressed in MDR is still unclear (last information from NB TÜV SÜD in April 2018)

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What to do?

- **Plan to update your CE-Dossier / Technical Documentation:** Be aware that also the technical file of class I devices has to be updated by DoA May 25th, 2020 even if no NB is reviewing the documents

- **Check the classes of your devices**: New classification rule implemented, check all products/Product groups regarding the new classification

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What to do?

- **Check the need of NB and look for one suitable NB:** If your products go from Class I to a higher class, you do need a notified body (Also for some IVDs the involvement of NB is required by 2022)
  Availability of NB capacity is expected to get problematic, because some NB do not ask for re-accreditation or may not going to be accreditated for the complete product range. Look for a suitable NB as soon as possible.

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What to do?

- **Check the possibility and need to stay with MDD-EG-Certifcates by end of transition phase** : If you are sure that no significant (potential effect on safety or effectivness) changes with your product will happen and the product should be discontinued by phasing out

- **Check the possibility of products discontinuation**: If you plan to discontinue products to avoid workload for legacy products, make the decision. If your company plan to sell the “Legacy“ products to countries outside EU be aware that a significant number of countries rely on the CE-Mark. These countries ask for Free-Sales-Certificates or requires CE-Mark for registration.

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Summary

- Way from MDD to MDR is not related to certificates only, even if the certificates are one significant component for the evaluation of conformity
- As Legal Manufacturer of Class I Products start work on / review of CE-Dossier/ Technical Documentation as soon as possible
- Pay attention to the changes with regards to all products and the range of application / intended use, this could affect the needed efforts substantially
- Be aware of the additional “Non-Product-Related“-Requirements, like UDI, Vigilanz-System etc.
- Start work with the NB as soon as possible and plan the timelines and the utilzation of the transition period together

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Contact data

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