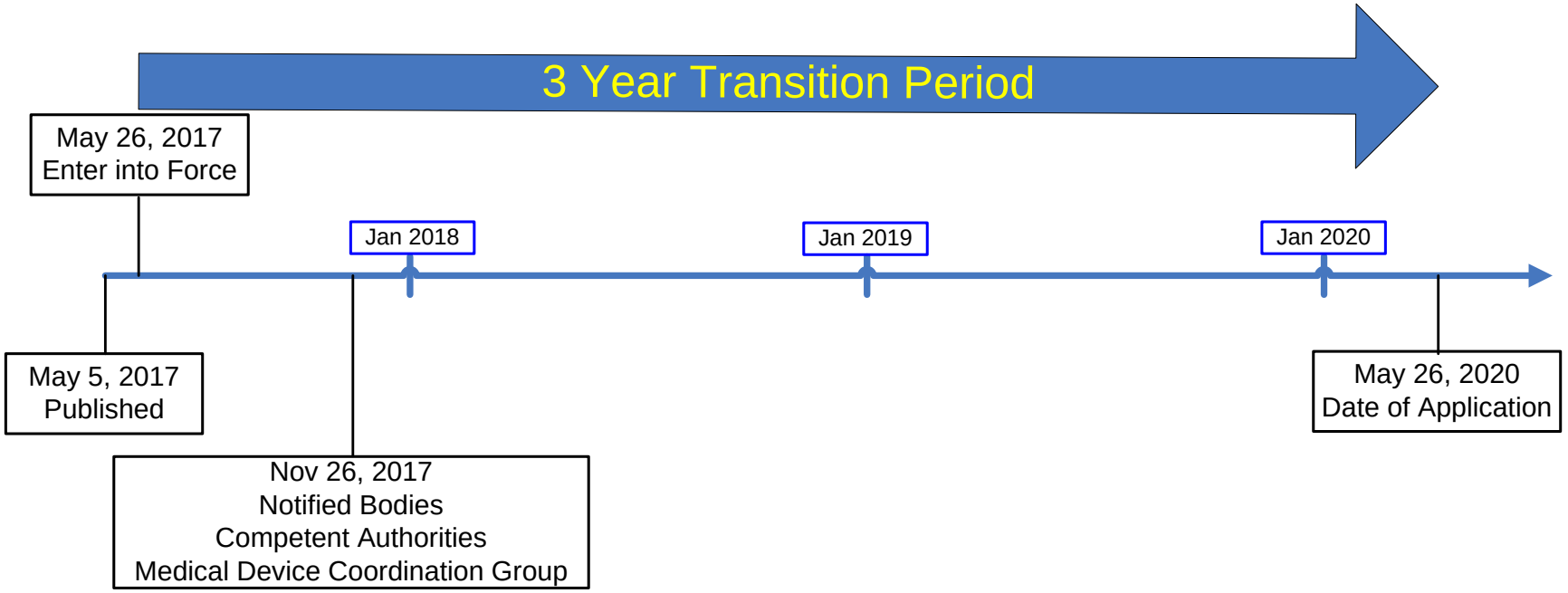
EU-MDR Transition Time Lines

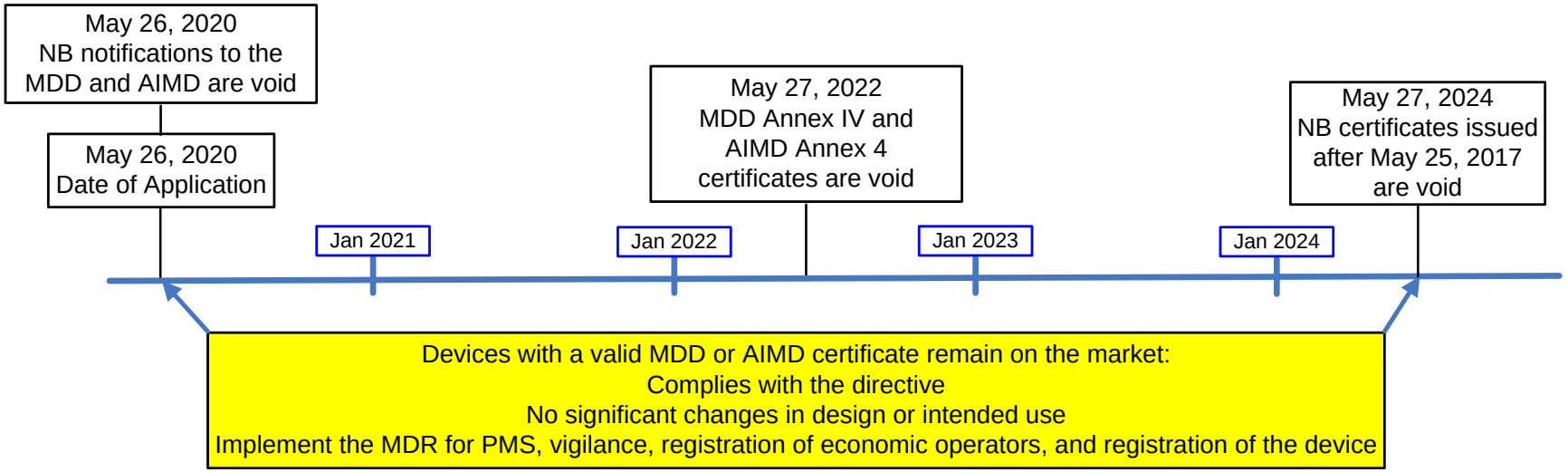
The EU published the official version of both the Medical Device Regulation (MDR) and In Vitro Diagnostic Device Regulation (IVDR) on May 5, 2017. The final versions include a timelines. The diagrams and the text below summarize the MDR requirement.



MDR Article 123 — Entry into Force and Date of Application

- Enters into force on May 26, 2017 – the 20th day following publication in the Official Journal
- It applies (date of application) from May 26, 2020 with some exceptions:
    - Notified Body, Competent Authority, and Medical Device Coordination Group provisions start November 26, 2017
    - If Eudamed is not fully functional on May 26, 2020, then the requirements apply six months after publication of a notice in the Official Journal
    - UDI carriers on the label and packaging:

        - Implantable devices and Class III devices — May 26, 2021
        - Class IIa and Class IIb devices — May 26, 2023
        - Class I devices — May 26, 2025
    - The coordinated assessment procedure for clinical investigations starts May 26, 2027



MDR Article 120 — Transitional Provisions

- From May 26, 2020 notification of Notified Bodies to the MDD or AIMD are void
- NB certificates for the MDD or AIMD issued before May 25, 2017 are valid for the stated term except:
    - MDD Annex IV and AIMD Annex 4 are void on May 27, 2022
    - NB certificates for the MDD or AIMD issued after May 25, 2017 are valid for the stated term, but are void on May 27, 2024
- Devices with a valid MDD or AIMD NB certificate may remain on the market provided:
    - From the date of application of the regulation (May 26, 2020) it complies with the directive
    - There are no significant changes in design or intended use

    - The manufacturer applies the regulation's requirements for market surveillance, post-market surveillance, vigilance, registration of economic operators, and registration of devices
- Devices that comply with the MDR may be marketed before May 26, 2020
- Notified Bodies may be notified before May 26, 2020 and may issue certificates to the MDR
- Clinical investigations to the MDD or AIMD started before May 26, 2020 may continue, but after that date the MDR applies for reporting serious adverse events and device deficiencies