

MEDICAL DEVICES

Regulatory Affairs Directorate
Technical Regulations Division

May 2019

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- Managing potential shortages

Introduction

Medical Devices Regulation (2017/745/EU) (MDR) and In-Vitro Diagnostic Medical Devices Regulation (2017/746/EU) (IVDR):

1. In line with technical advances, changes in medical science, and progress in law making
2. Create a robust, transparent and sustainable regulatory framework, recognised internationally, that improves clinical safety and creates fair market access to manufacturers
3. Compared to Directives, Regulations do not need transposition into national law therefore reduce risks of discrepancies in interpretation across the EU market

Timeline

- MDR and IVDR: 3 year (2020) and 5 year (2022) transition period respectively
- During transition period: devices can fall under current EU Directives or the new MDRs
- Designation process for NBs: ≥ 12 months for each designation taking a significant part of the transition period
- Limited time for manufacturers to get all products re-certified under new regulations. An extended period after date of application of regulation for re-certification for most devices to avoid disruption and unavailability
- After transition period: devices must comply with MDR & IVDR (unless they wish to make use of the extended period of CE certificate validity)

MDD devices without significant changes in design & intended purpose may be continued to be made available on the market.*

MDD certificates issued prior to 25 May 2017 shall remain valid until the end of the period indicated on the certificate.* (shall not exceed more than 5 yrs from date of issue & certificate shall be void latest on 27 May 2024) (Article 120(2))

Class Is, Im, IIa, IIB, III, AIMD devices - MDD placing the market is possible (=first making available)

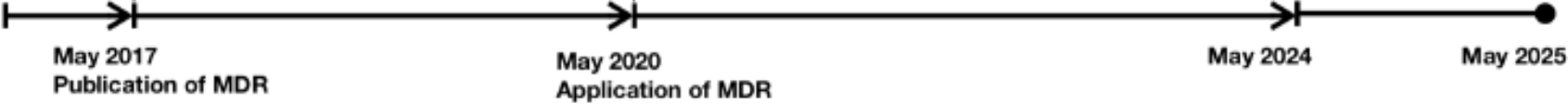
Class I devices - MDD placing the market is possible (=first making available)

NB to stop issuing certifications accordingly to MDD. Beyond 26 May 2020 any publication of a notification with MDD shall become void Article 120(1)

First NB designations finalised & NB can start to issue certifications in compliance with the MDR Article 120(6)

MDR devices can be placed on the market prior to May 2020 (Article 120(5)) provided that the necessary appointments to the MDCG and expert panels have been made. (Article 120(7))

approx 18months from publication

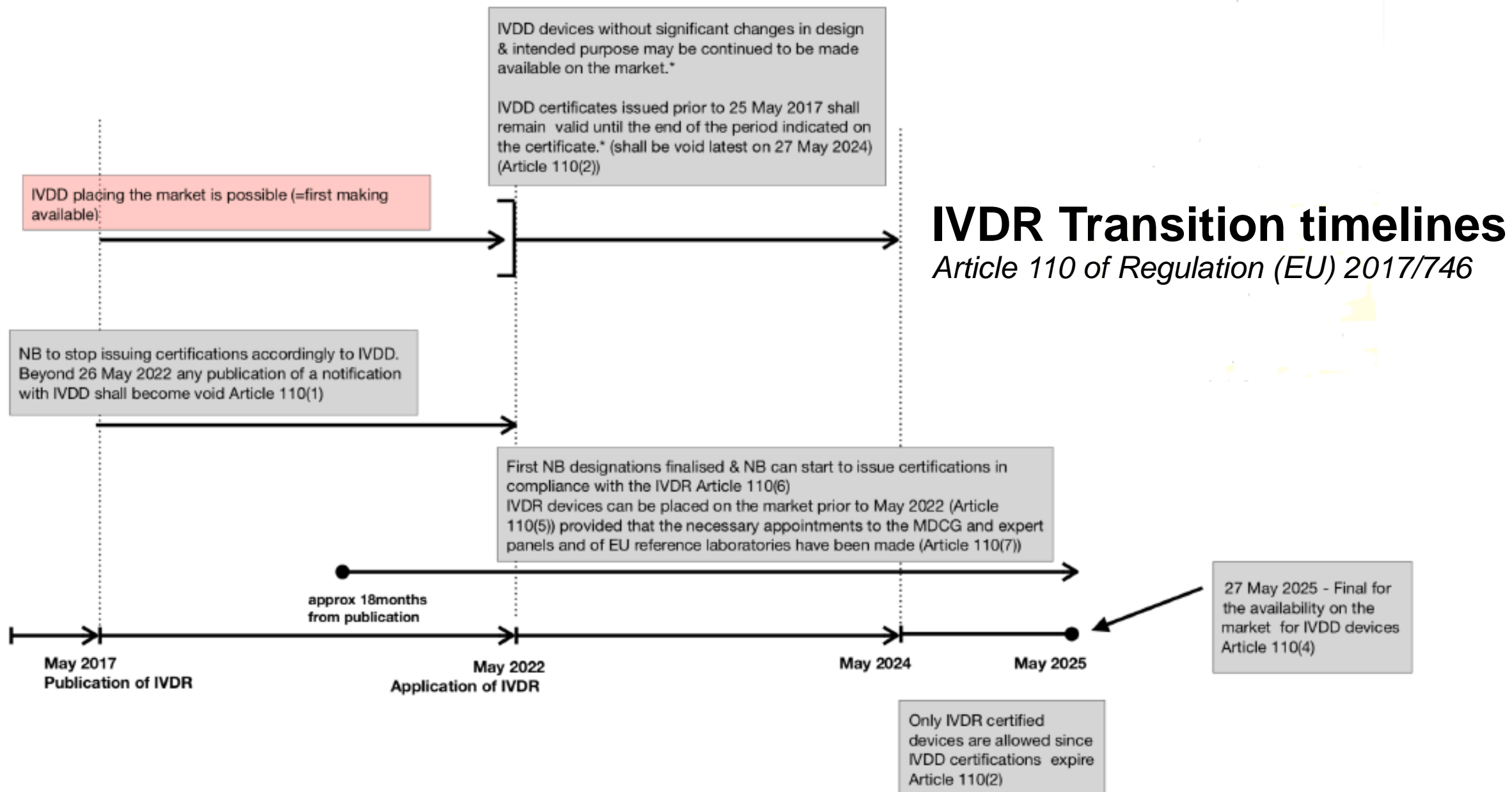


Only MDR certified devices are allowed since MDD certifications expire Article 120(2)

27 May 2025 - Final for the availability on the market for MDD & AIMD devices Article 120(4)

MDR Transition timelines

Article 120 of Regulation (EU) 2017/745



Brexit

Medical Devices in case of a 'no deal' scenario

- The Commission and Member States have been closely monitoring the progress of transfers of certificates from UK Notified Bodies to EU27 notified bodies
- In justified cases where derogations are granted, UK certificate holders will be allowed to continue placing their products on the EU27 market for a limited period of time.

Managing potential shortages

- The Commission is working closely with EU27 Member States to monitor the progress of certificate transfers and to identify critical medical devices that may be at risk of shortages.
- The Commission will coordinate and ensure transparency with regard to derogations for medical devices certified by a UK notified body. This will ensure a coherent approach and avoid any fragmentation of the internal market.

THANK YOU!

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