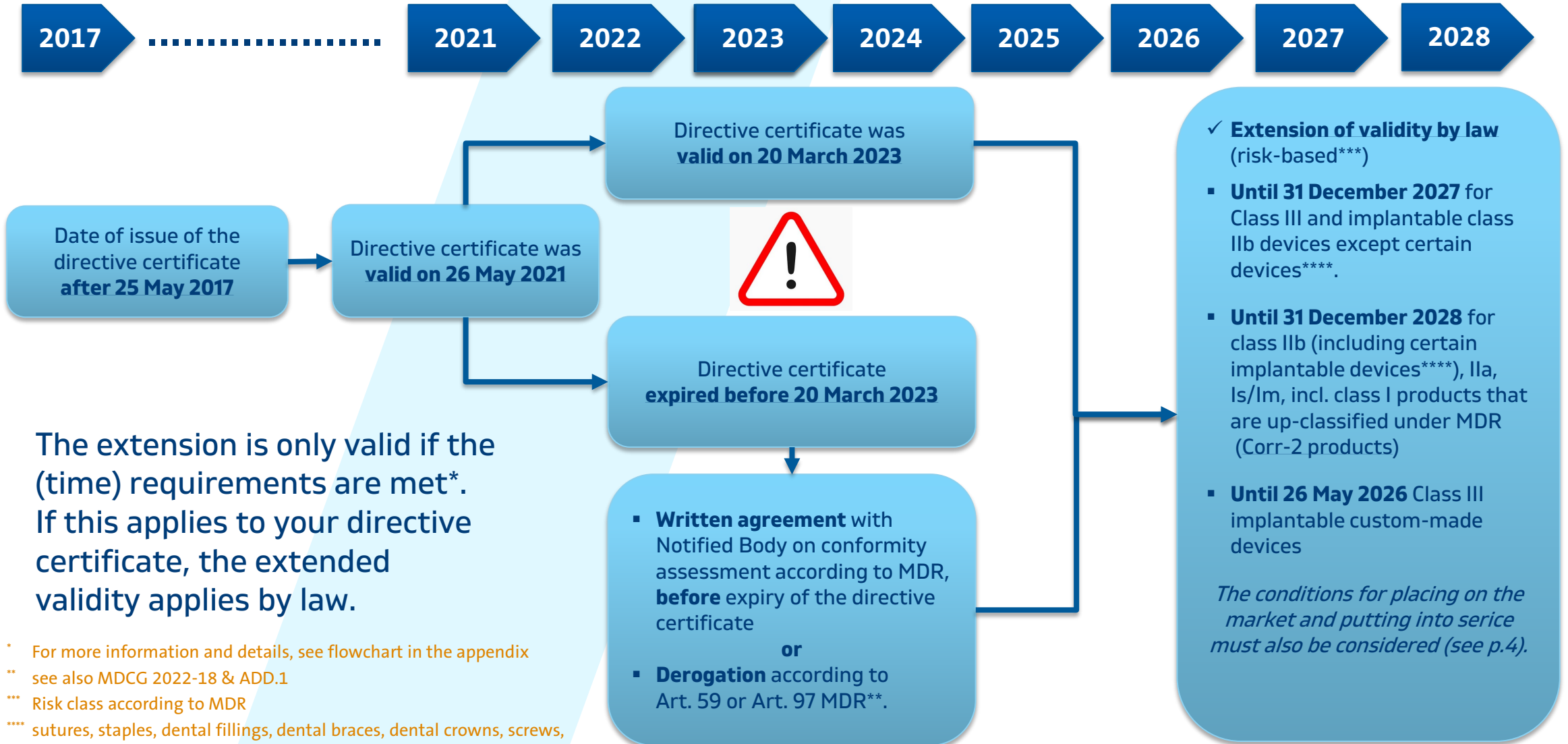


## **#MDRReady | Factsheet**

# **Placing on the market of medical devices ("legacy devices") under the MDR according to Regulation (EU) 2023/607 of 20 March 2023 (2<sup>nd</sup> MDR Amendment)**

- Extended validity of directive certificates
- Extended transition periods
- Conditions for placing on the market and putting into service
- Removal of sell-off period

# Requirements for the extension of directive certificate validity



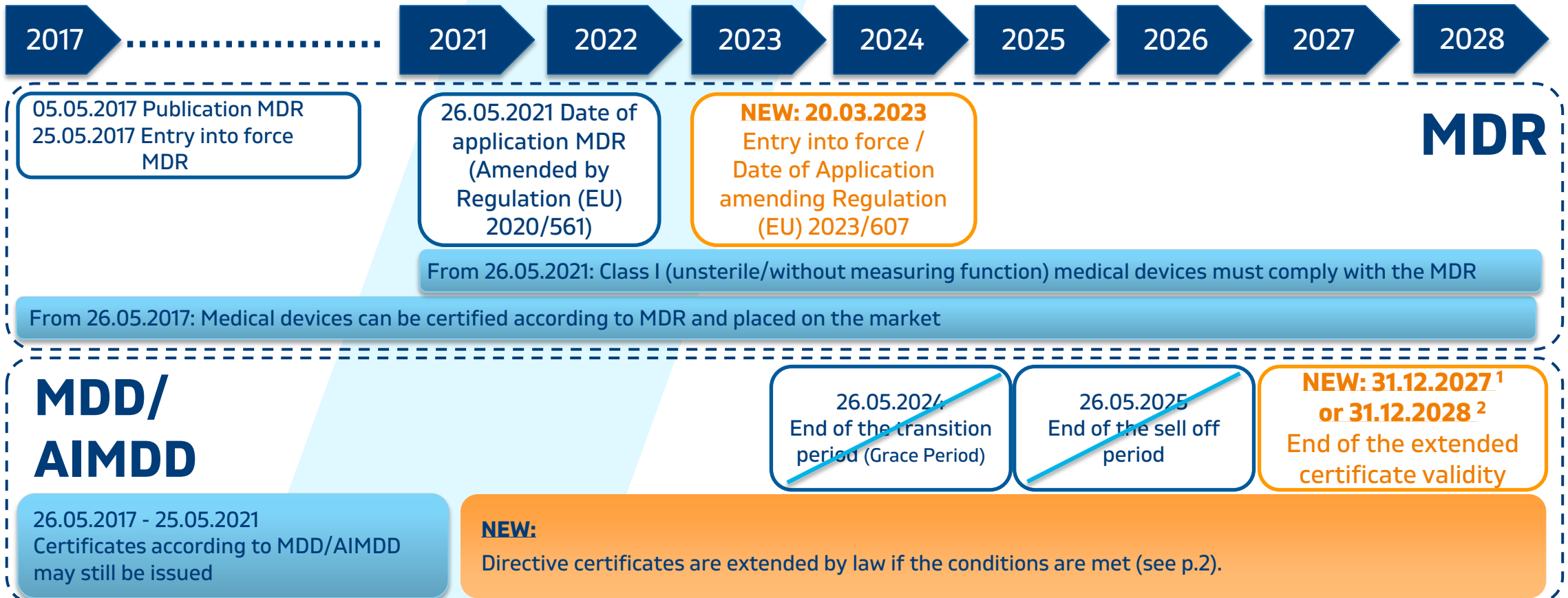
The extension is only valid if the (time) requirements are met\*. If this applies to your directive certificate, the extended validity applies by law.

\* For more information and details, see flowchart in the appendix  
 \*\* see also MDCG 2022-18 & ADD.1  
 \*\*\* Risk class according to MDR  
 \*\*\*\* sutures, staples, dental fillings, dental braces, dental crowns, screws, wedges, dental or bone plates, wires, pins, clamps and connectors

# Extended validity of directive certificates

Extension by law, if certain conditions are met.

The Amendment Regulation has no influence on MDR certificates



<sup>1</sup> Class III devices and for implantable devices in Class IIb with the exception of sutures, staples, dental fillings, dental braces, dental crowns, screws, wedges, dental or bone plates, wires, pins, clamps and connectors.

<sup>2</sup> Other class IIb devices, class IIa devices and for class I devices placed on the market in a sterile condition (class Is) or with a measuring function (class Im) and „Corr-2“ devices

# Conditions for placing on the market / putting into service of legacy devices



- Directive certificate must be valid in the context of the 2nd Amendment, according Art. 120 (2) MDR
- Products must continue to comply with the Directives (MDD/AIMDD) and fulfil the conditions set out in Art. 120 (3d) MDR: post-market surveillance, market surveillance, vigilance, registration of economic operators and of products.
- No significant change according to [MDCG 2020-3 Rev.1](#)

**NEW:** the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health

Legacy Devices may only be placed on the market or put into service if all conditions are met.

- NEW: no later than 26 May 2024**
- the manufacturer's quality management system must comply with the MDR
  - the manufacturer or auth. rep. must have submitted a formal application for conformity assessment to a Notified Body

- **NEW: No later than 26 September 2024**, a written agreement/contract regarding conformity assessment must have been concluded between the manufacturer and the notified body
- **NEW (when changing the Notified Body, if applicable): no later than by 26 September 2024**, the transfer of surveillance of the manufacturer and the QMS to the new Notified Body according to MDR takes place.

## Other relevant documents:



Source Unsplash

- EU Commission Q&A Rev.1 (July 2023) "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"
- Voluntary Manufacturer's Declaration in relation to Regulation (EU) 2023/607
- Template for NB - Confirmation letter in the framework of Regulation (EU) 2023/607
- Flowchart to assist in deciding whether or not a device is covered by the extended MDR transitional period
- MDCG Guidance 2020-3 Rev.1 "Guidance on significant changes regarding the transitional provision under Article 120 of the MDR - May 2023"
- MDCG Guidance 2022-18 "MDCG Position Paper on the application of Article 97 MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate" & ADD.1 "Addendum 1"
- MDCG Guidance 2022-14 "Transition to the MDR and IVDR Notified body capacity and availability of medical devices and IVDs"

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