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Transition Periods

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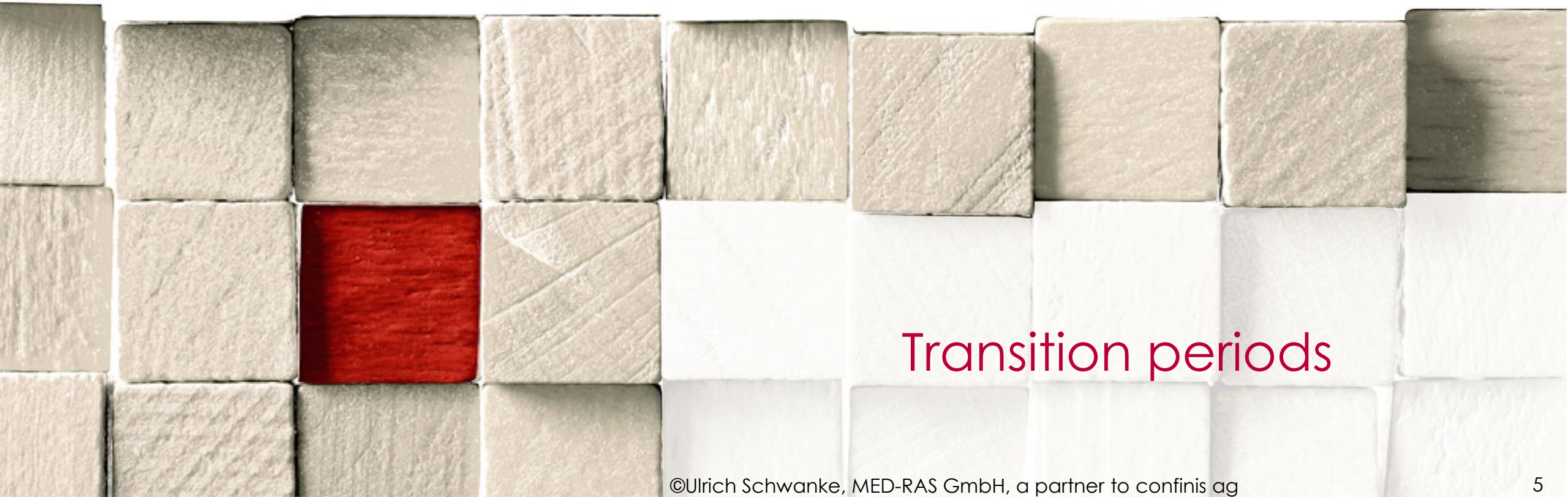

Transition periods

Article 123 1|3

- 3 years after entry into force for the Regulation on **medical devices**: 26th of May 2020.
- All articles for notified bodies (35-50) shall apply from 26th November 2017.
- Cooperation between Member States, Medical Device Coordination Group, etc. from 26. November 2017 and 26. May 2018.

Article 123 2|3

- **Functionality of Eudamed (Article 34)**

- The Commission shall draw up the functional specifications for Eudamed and shall draw up a plan for the implementation of those specifications by 26 May 2018.

- Eudamed shall be fully functional at last by 26 March 2020 (minus time for publish of notice).

- Inputs in Eudamed are mandatory 18 months after full functionality for manufacturers and notified bodies.

Article 123 3|3

- **UDI Labeling (Article 27 (4)):**
  - For implantable devices and for class III devices : 26 May 2021
  - For class IIa and class IIb devices: 26 May 2023
  - For class I devices: 26 May 2025
  - For re-usable devices (UDI labeling on the product): in each case two years later
  - Until the Commission has designated issuing entities (for UDI Article 27 (2)), GS1, HIBCC and ICCBBA shall be considered to be designated issuing entities: 26 May 2019
- **Coordinated assessment procedure for clinical investigations (Article 78)**
  - Shall apply by 26 May 2027 (each country can decide to follow the procedure earlier)