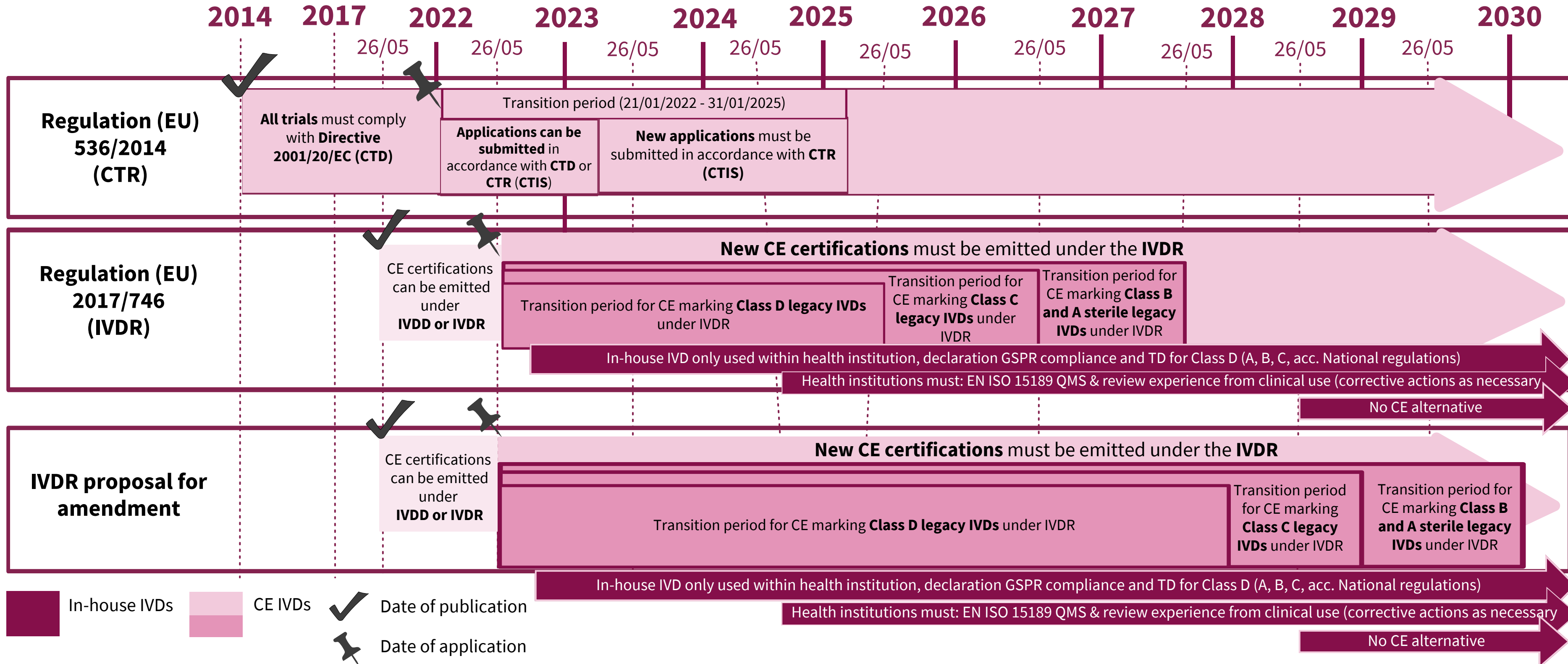


# Proposal for amending In vitro diagnostic medical devices Regulation (EU) 2017/746 (IVDR)



# Proposal for amending In vitro diagnostic medical devices Regulation (EU) 2017/746 (IVDR)



2014 2017 2022 2023 2024 2025 2026 2027 2028 2029 2030

26/05 26/05 26/05 26/05 26/05 26/05 26/05 26/05 26/05 26/05

**Regulation (EU) 536/2014 (CTR)**

All trials must comply with **Directive 2001/20/EC (CTD)**

Transition period (21/01/2022 - 31/01/2025)

Applications can be submitted in accordance with CTD or CTR (CTIS)

**New applications** must be submitted in accordance with **CTR (CTIS)**

All trials must comply with **CTR (CTIS)**

**Regulation (EU) 2017/746 (IVDR)**

**New CE certifications** must be emitted under the **IVDR**

CE certifications can be emitted under **IVDD or IVDR**

Transition period for CE marking **Class D legacy IVDs** under IVDR

Transition period for CE marking **Class C legacy IVDs** under IVDR

Transition period for CE marking **Class B and A sterile legacy IVDs** under IVDR

In-house IVD only used within health institution, declaration GSPR compliance and TD for Class D (A, B, C, acc. National regulations)

Health institutions must: EN ISO 15189 QMS & review experience from clinical use (corrective actions as necessary)

No CE alternative

**IVDR proposal for amendment**

**New CE certifications** must be emitted under the **IVDR**

CE certifications can be emitted under **IVDD or IVDR**

Transition period for CE marking **Class D legacy IVDs** under IVDR

Transition period for CE marking **Class C legacy IVDs** under IVDR

Transition period for CE marking **Class B and A sterile legacy IVDs** under IVDR

In-house IVD only used within health institution, declaration GSPR compliance and TD for Class D (A, B, C, acc. National regulations)

Health institutions must: EN ISO 15189 QMS & review experience from clinical use (corrective actions as necessary)

No CE alternative

In-house IVDs

CE IVDs



Date of publication



Date of application

# Proposal for amending In vitro diagnostic medical devices Regulation (EU) 2017/746 (IVDR)



2014 2017 2022 2023 2024 2025 2026 2027 2028 2029 2030

26/05 26/05 26/05 26/05 26/05 26/05 26/05 26/05 26/05 26/05

**Regulation (EU) 536/2014 (CTR)**

All trials must comply with **Directive 2001/20/EC (CTD)**

Transition period (21/01/2022 - 31/01/2025)

Applications can be submitted in accordance with CTD or CTR (CTIS)

**New applications** must be submitted in accordance with **CTR (CTIS)**

All trials must comply with **CTR (CTIS)**

**Regulation (EU) 2017/746 (IVDR)**

CE certifications can be emitted under **IVDD or IVDR**

**New CE certifications** must be emitted under the **IVDR**

Transition period for CE marking **Class D legacy IVDs** under IVDR

Transition period for CE marking **Class C legacy IVDs** under IVDR

Transition period for CE marking **Class B and A sterile legacy IVDs** under IVDR

In-house IVD only used within health institution, declaration GSPR compliance and TD for Class D (A, B, C, acc. National regulations)

Health institutions must: EN ISO 15189 QMS & review experience from clinical use (corrective actions as necessary)

No CE alternative

**IVDR proposal for amendment**

CE certifications can be emitted under **IVDD or IVDR**

**New CE certifications** must be emitted under the **IVDR**

Transition period for CE marking **Class D legacy IVDs** under IVDR

Transition period for CE marking **Class C legacy IVDs** under IVDR

Transition period for CE marking **Class B and A sterile legacy IVDs** under IVDR

In-house IVD only used within health institution, declaration GSPR compliance and TD for Class D (A, B, C, acc. National regulations)

Health institutions must: EN ISO 15189 QMS & review experience from clinical use (corrective actions as necessary)

No CE alternative

In-house IVDs

CE IVDs



Date of publication



Date of application