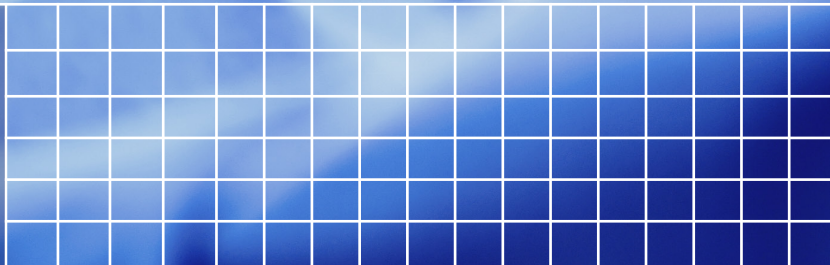




## Guidance to compliance with the **In vitro Diagnostic Regulation (EU) 2017/746**

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# Guidance to compliance with the **In vitro Diagnostic Regulation (EU) 2017/746**

## Some basic facts

- The IVDR was adopted in April 2017, entered into force in May 2017 and will apply from 26 May 2022.
- **From 26 May 2022**, notified bodies will not...

- As of 27 May 2025, any IVD device...

## 29 Steps to the CE Marking under IVDR

- Step 1:** Ensure your device meets the definition of an in vitro diagnostic medical device.
- Step 2:** [...]