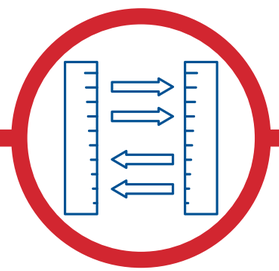
1. What is new in the IVDR and what does it entail?

There will be stricter regulations on CE-IVDs and laboratory developed diagnostic tests, also known as in-house devices (IH-IVDs).

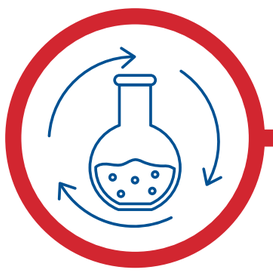
All new and existing CE-IVDs will be reclassified using a system based on risk to patients and the public.

The majority of IVD Directive (IVDD) self-declared products must be certified by a notified body according to the IVDR.



Use of IH-IVDs will be restricted if an equivalent CE-IVD is available on the market.

Laboratories that continue to use IH-IVDs are subject to stricter requirements and must meet ISO 15189 requirements or applicable national provisions.



Existing CE-IVDs are in danger of disappearing from the market if their manufacturers lack the knowledge, incentives, or budget to go through the notified bodies appraisal.

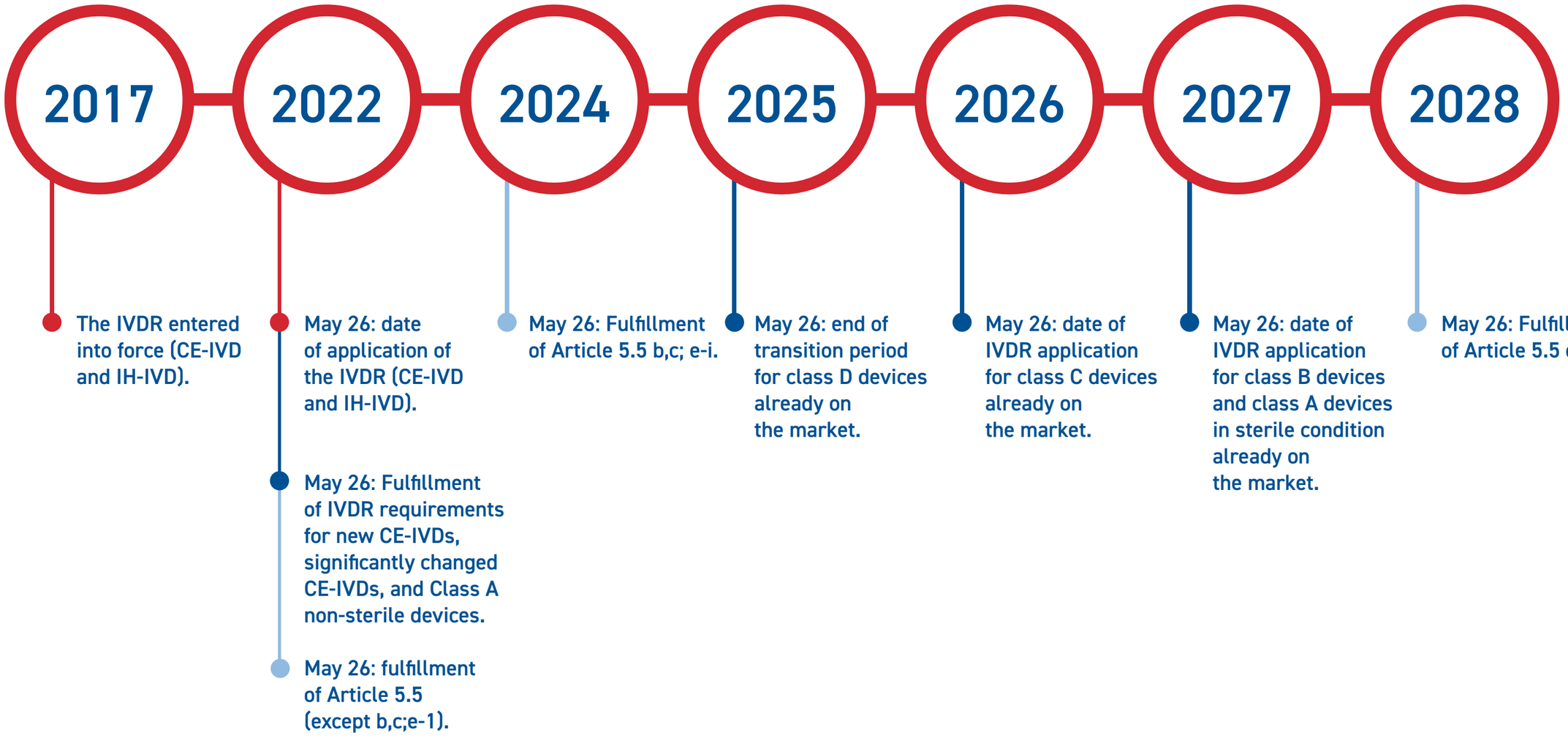
2. How can diagnostic hematology laboratories prepare for the IVDR?

1. Create a dedicated team to study and assess the requirements and impacts of the IVDR.

2. Compile an assay inventory to assess the impact of the IVDR on your test portfolio (CE-IVD and IH-IVD)

3. Ensure regulatory compliance for IH-IVDs by generating and updating the relevant processes and documents.

3. What is the current timeline for the IVDR implementation?



- Applicable to CE-IVDs and IH-IVDs
- Applicable to IH-IVDs
- Applicable to CE-IVDs

IH-IVDs receive additional transition time.

CE-IVDs have additional transitional provisions according to their risk class.

4. What are the new IVDR risk classes?

Classification	Individual Health Risk		Public Health Risk
Class A IVD	Low	and	Low
Class B IVD	Moderate	and	Low
Class C IVD	High	and/or	Moderate
Class D IVD	High	and	High