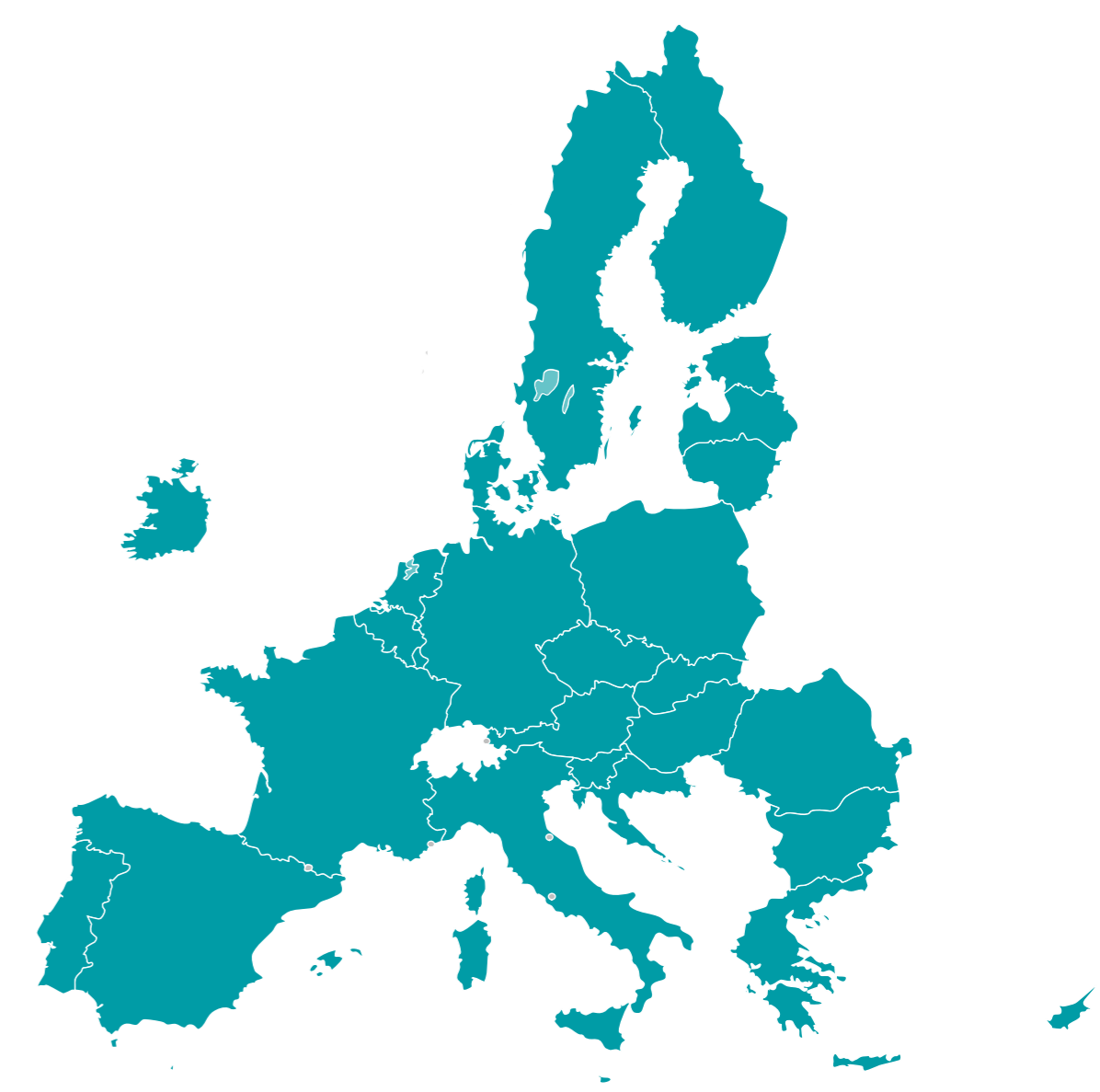


# THE European Union In Vitro Diagnostic Medical Device Regulation (IVDR)



## About the European Union (EU)

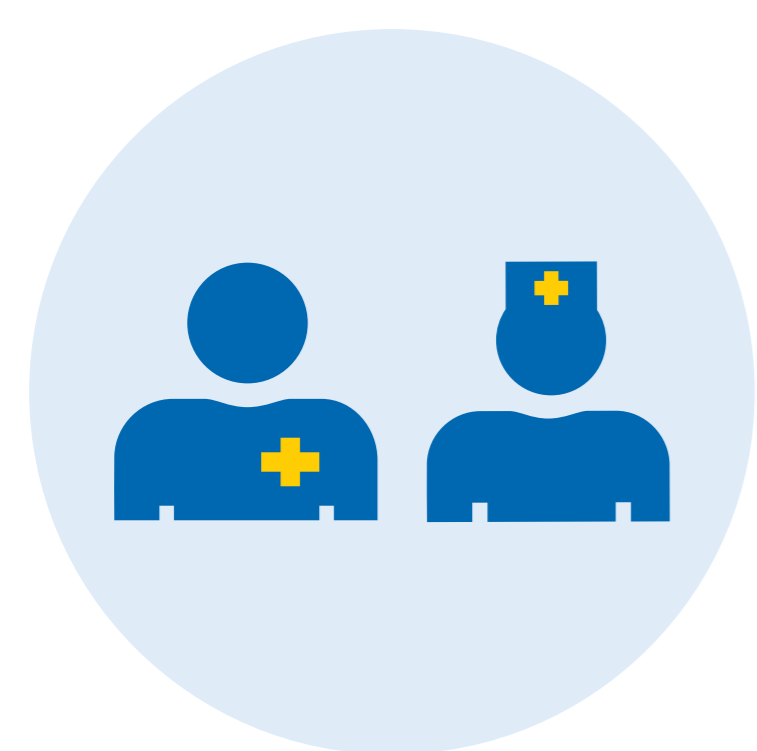


The EU population numbers more than **445 million people**.

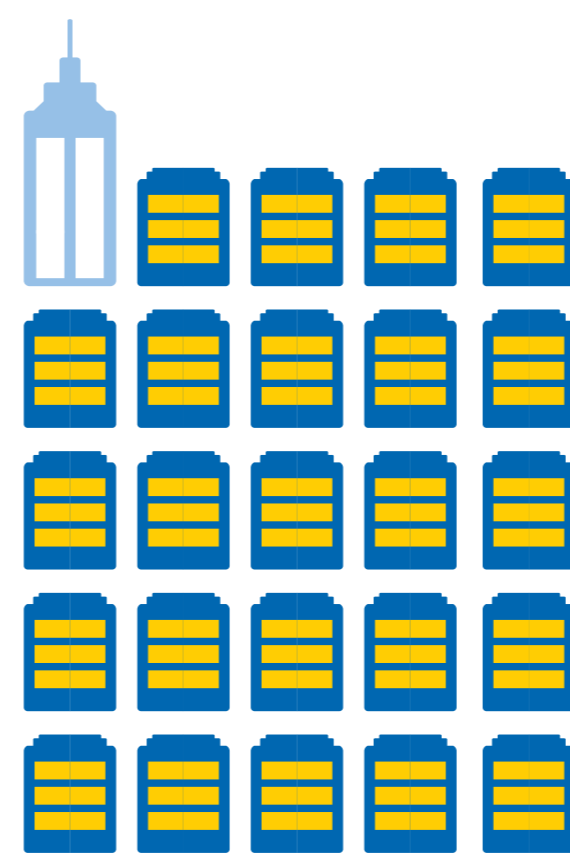


The total medical device sales in the EU is close to **EUR 140 billion.\***

Source: <https://www.medtecheurope.org/wp-content/uploads/2021/06/medtech-europe-facts-and-figures-2021.pdf>



The European medical device industry employs approx. **760,000.\***



The European medical device sector is comprised of **33,000 companies**.

Source: <https://www.emergobyul.com/resources/market-europe>

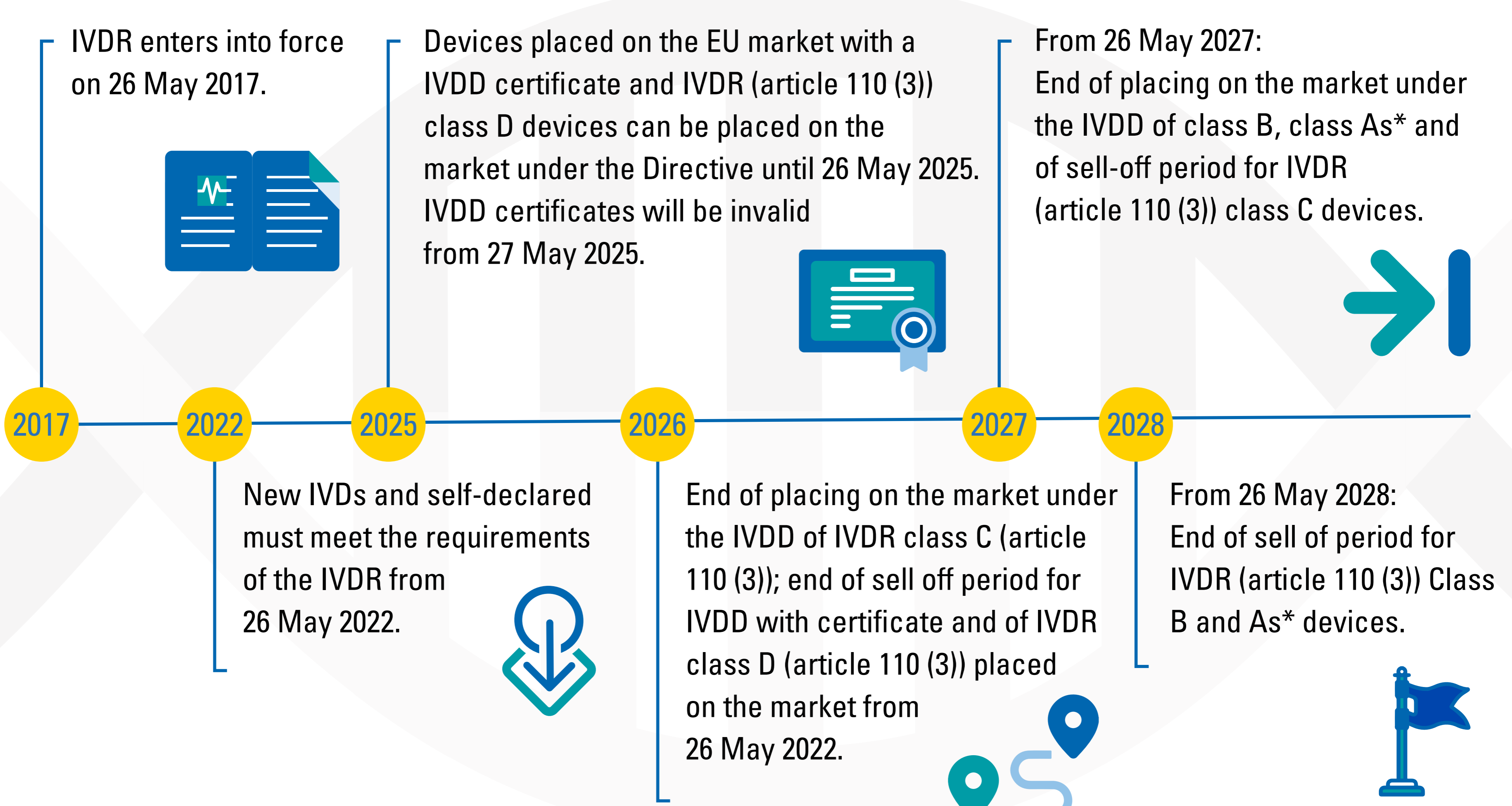
## What is the IVDR?

The IVDR is the regulatory basis for placing on the market, making available and putting into service in vitro diagnostic medical devices on the European market. It will replace the EU's current Directive on in vitro diagnostic medical devices (98/79/EC). As a European regulation, it will be effective in all EU member states and EFTA states immediately without need to be transferred into the law of respective states, however national laws may be adapted to back up some requirements in more detail.



Following the publication of regulation (EU) 2022/112, the IVDR will be rolled out gradually. Find out more in the timeline section below.

## Timeline of the IVDR

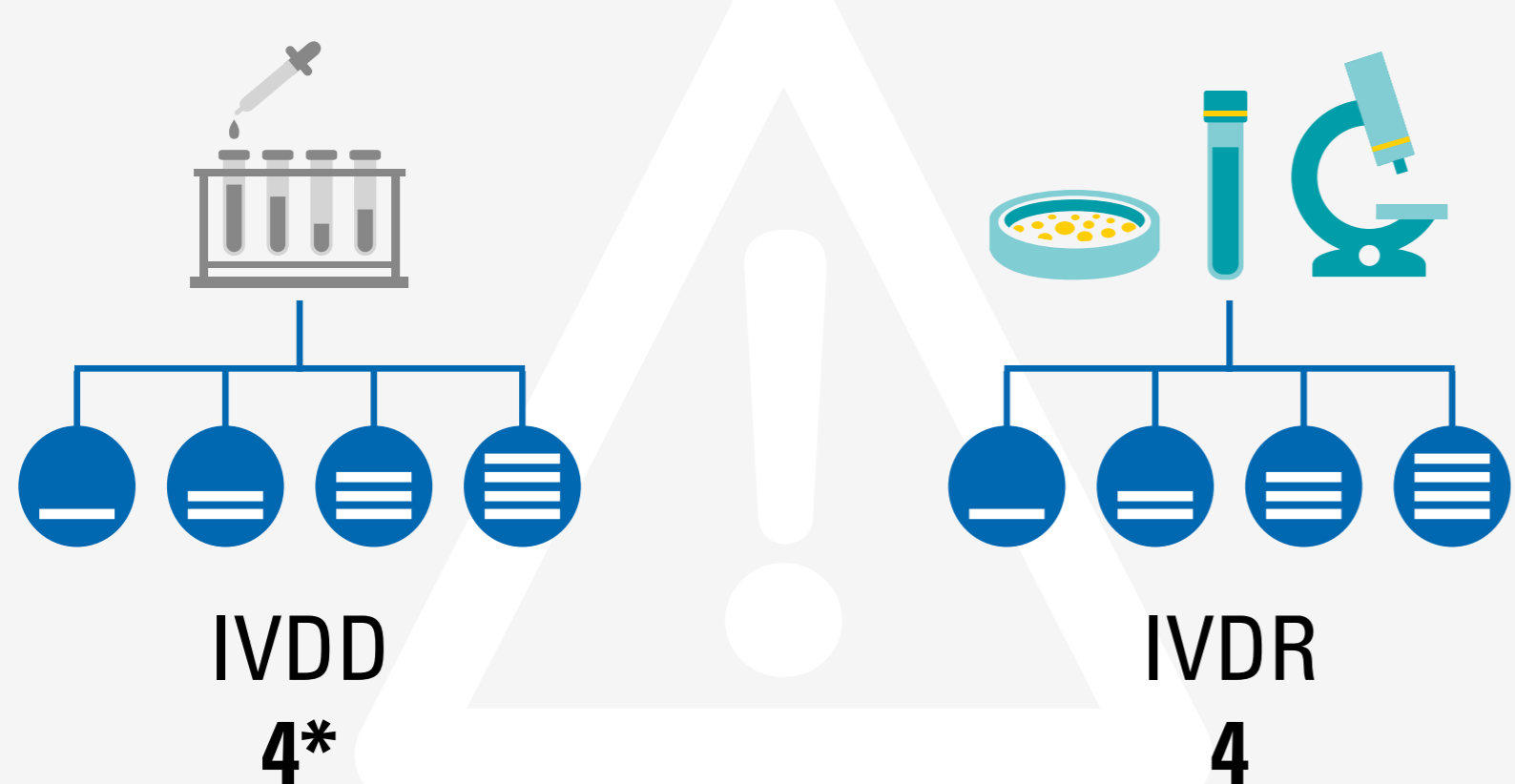


From the 26 May 2022, the requirements of the IVDR related to post-market surveillance, vigilance, registration of economic operators and of devices will apply to all IVDs.

Regardless of the device risk class, if a significant change to design and intended purpose is done, the IVD will need to comply with the IVDR as soon as the change(s) are implemented.

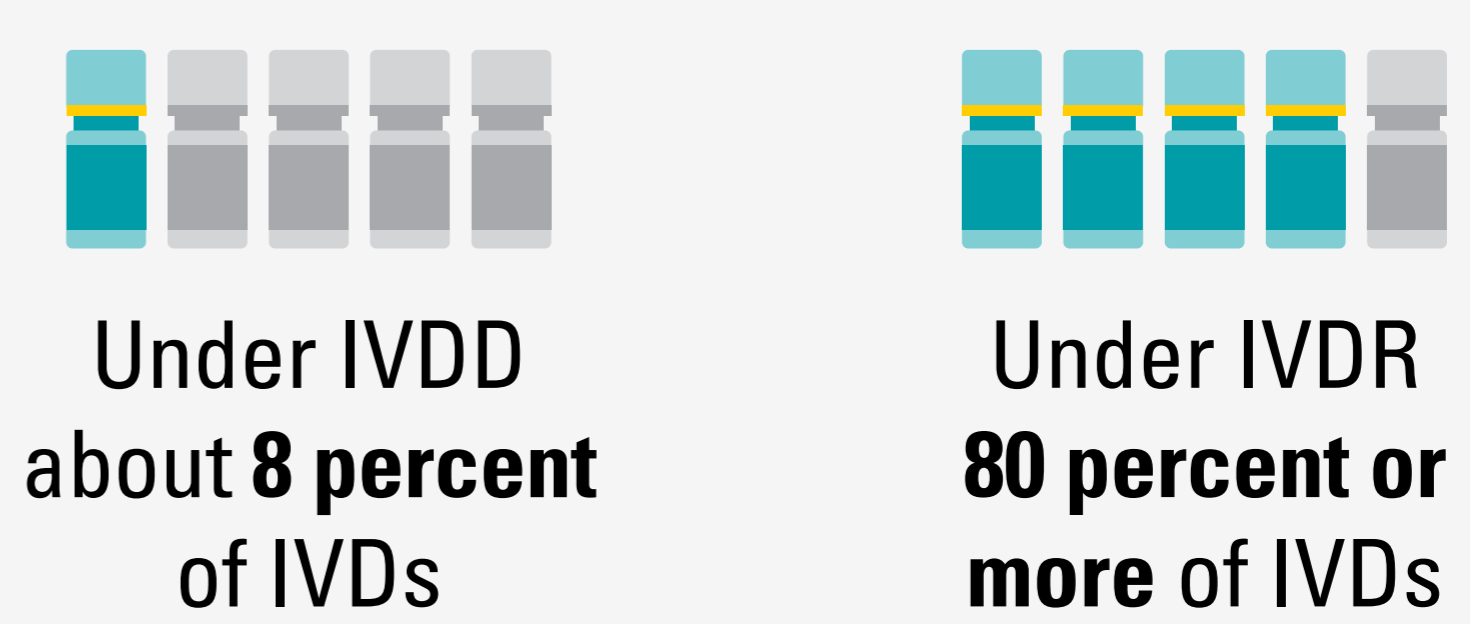
\*As: Class A devices placed on the market in sterile conditions

## Risk classes



\*Risk not consequently considered except for high risk products.

## Notified Body involvement



## Key changes



Product scope expansion



Re-classification according to risk



More stringent clinical evidence



Identification of person responsible for regulatory compliance



More stringent documentation



Implementation of unique device identification



Rigorous post-market oversight



Increased Notified Body involvement



Get ready for the new In Vitro Diagnostic Device Regulation now  
[www.tuv-sud.com/ivdr](http://www.tuv-sud.com/ivdr)