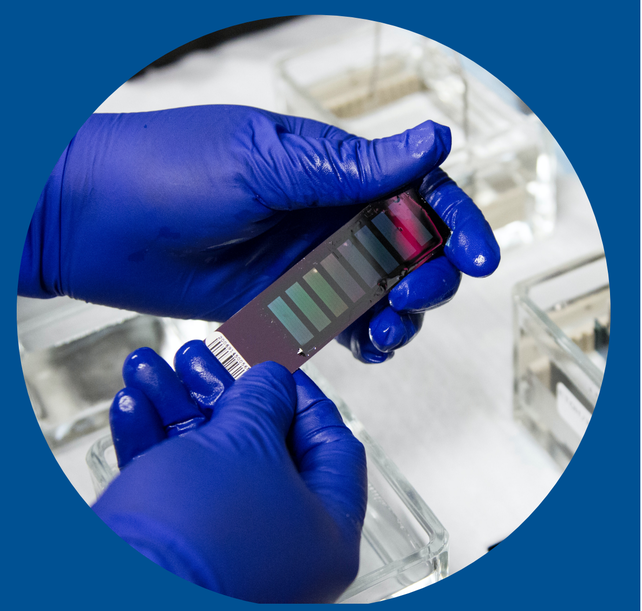
EUROPEAN HEMATOLOGY ASSOCIATION

What does the new EU Regulation on In Vitro Diagnostic medical devices (IVDR) mean for you?



What is the IVDR?

As of **May 26, 2022**, the new EU In Vitro Diagnostic medical devices Regulation (IVDR) comes into effect. Whereas the previous directive was open to national interpretation, the IVDR is not and must be applied in its entirety across the EU. The IVDR mandates stricter and more comprehensive certification and testing protocols for in vitro diagnostic devices. This has a major impact on commercially available IVDs (CE-IVD) devices and important consequences for in-house IVDs (IH-IVD) devices.

1 How will the IVDR impact your lab?

- Stricter regulations on which laboratory developed diagnostic tests, also known as IH-IVDs, may be used.
- 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-certified 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.
- 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 your lab prepare for the IVDR?

1. Create a dedicated team to study and assess the requirements and impacts of the IVDR.
2. Compile an assay portfolio inventory to understand the impact on CE-IVDs and IH-IVDs.
3. Ensure regulatory compliance for IH-IVDs and identify areas where further information on IVDR compliance is required.

3 What does EHA do to help?

EHA engages with EU authorities, aligns with fellow diagnostic disciplines through the BioMed Alliance, and raises awareness of upcoming regulations among laboratory hematologists, clinicians, and researchers.

Resources:

HemaSphere Article on the IVDR

EHA Congress Session on Diagnostic Regulations

BioMed Alliance Statement on the IVDR Implementation

If you want to know more or need help preparing for the IVD, please contact us at IVDR@ehaweb.org