The new IVDR (EU IVDR 2017/746) will ensure that IVD (in vitro diagnostics) products, achieve the highest levels of safety and efficacy possible. Laboratory-developed tests (LDT)/in-house devices (IH-IVD), which constitute a majority of the clinical flow cytometry tests, will now be regulated by the new IVDR.

Under the new regulation, flow cytometry laboratories who desire to build their own cocktail of conjugated antibodies for diagnostic purposes can either use:

- Non CE-marked monoclonal antibodies (mAbs) Cocktail (R&D, and/or off-label use of CE marked mAbs) and bring their cocktail in compliance with IVDR or ensure all article 5.5 requirements are met, including among others compliance with Annex I General Safety & Performances requirements, ISO1384 or other national provision related to accreditation, justify the absence of equivalent devices commercially available, plus adaptations to the GMS to make it appropriate for design and manufacturing.
- A CE-marked mAbs Cocktail in line with each mAb Instruction for Use (IFU) and intended purpose. The laboratories are not affected by the IVDR and might only have to perform either performance verification or validation, very similar to the current process.

The use of CE-marked mAbs cocktails necessitates that all mAbs have Intended Purposes that are consistent with the application (Article 5.1).