The key differences between MDR and IVDR in the EU

In the European Union (EU), two significant regulations have been introduced to enhance the safety and effectiveness of medical devices – the In Vitro Diagnostic Regulation (IVDR) and the Medical Device Regulation (MDR).

Navigating the regulatory landscape of medical devices in the European Union demands a thorough understanding of both the In Vitro Diagnostic Regulation (IVDR) and the Medical Device Regulation (MDR). While these regulations share commonalities, such as risk-based classification and conformity assessment, differences in scope, implementation dates, and the level of notified body involvement necessitate careful consideration from manufacturers. Adhering to these regulations is not only a legal requirement but a commitment to ensuring the safety and efficacy of medical devices for the well-being of patients.