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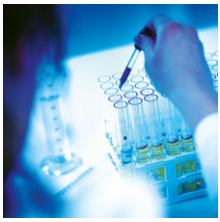
White paper

IVDR – it's time to act to stay on the EU market!

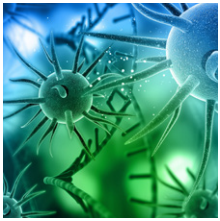
Introduction



The new In Vitro Diagnostic Regulation (IVDR) for devices on the EU market came into effect on 25 May 2017. From that date, a five-year transition period allows IVD device manufacturers to re-certify their existing devices to comply with the new regulation. After 26 May 2022, devices class B, C and D have to received re-certification by notified body (NB) to be legally placed on the EU market. Devices class A have to be re-registered at the competent authority for the same reason. Devices certified under the In Vitro Diagnostic Directive (IVDD), and under notified body supervision, have a transition period according to the validity of the EC-certificate as long as no significant changes are implemented.

The main aim of the new regulation is to increase transparency, traceability and end users' safety. Technological advances since the directives were first adopted have necessitated regulation updates to keep up with new innovations, materials and devices.

New technologies require improved regulations



By enforcing a set of rules less open to interpretation and by focusing on the entire lifecycle of a device rather than up to the point of approval, the regulations are a tool for better follow up how the devices perform once on the market.

2022 may seem far away, but a number of activities should already be underway to make sure devices get their approval according to IVDR before the end of the transition period.

While many of the requirements of the IVDR are the same as under IVDD, there are also some big differences between the two. IVDR governs not only the device and its manufacturer, but also distributors, importers and authorized representatives, where all carry legal responsibility for their activities. The regulation stipulates how manufacturers' quality management systems are to be designed and what they must include it introduces for example stricter requirements on technical documentation and post-market surveillance – all adding to the emphasis on the device lifecycle. Another change is the requirement on all manufacturers, as well as on Authorised Representatives, to have their own dedicated Person Responsible for Regulatory Compliance (PRRC) with a specified level of relevant training or work experience corresponding to the training required.

Classification rules will change considerably

One of the most important changes in the new regulation is the device classification system. What used to be two lists of device groups to choose from is now a risk-based system, where devices with higher risk will require surveillance and certification of an notified body. IVDs which do not clearly fit into a specific class are automatically classified as Class B, meaning that they have to be certified by an notified body.

Conclusion

There is doubtless a lot of work that needs to be done within a very limited timeframe. The workload for notified body's is certainly going to be significant during the transition period, which will make it one of the bottlenecks preventing some devices from getting approval from EU to get their certification in time.

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