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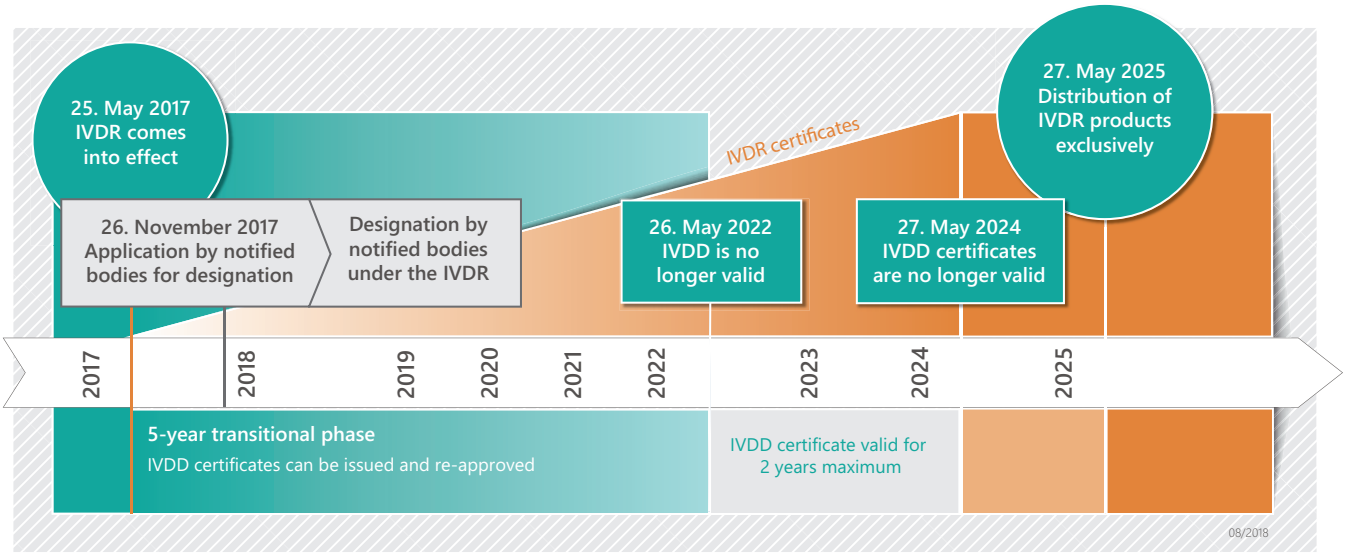
the service company



NEW IVDR In-vitro Diagnostic Medical Device Regulation
OLD IVDD In-vitro Diagnostic Devices Directive

IVD

Compliant with safety

In-vitro diagnostic devices (IVD) are the specialists among medical devices, complex and effective. Because of their special nature, IVD are governed by their own regulation (IVDR). The efficient interplay of the different quality management processes is intended to develop safe and effective devices and to maintain them through the whole product lifecycle.

In the technical documentation, you provide third parties with evidence that these processes are conducted properly and in compliance with the relevant country of destination. We help you to meet this requirement at all levels and at any time in the product life cycle.

The advantages for you

- We are your reliable partner in adapting your QM processes and producing and revising the technical documentation for your IVD.
- You will receive all documents for your technical documentation ready to sign on your templates for licensing (international) and/or device certification (EU).
- Our experience in both the documentation and certification process and in the verification and validation of IVD and medical devices ensures that we meet your targets rapidly and efficiently.
- Our GAP analyses supply recommendations for action on all levels of your regulatory activity (QM system, technical documentation, product portfolio).

OUR SERVICES:

Review and adaptation of quality management:

· Analysis of the need for change,
· Adapting processes.

Creation and care of technical documentation:

· Creating the contents of technical documentation (EU und international) – in compliance with standards and legislation,
· Testing of technical documentation for IVD already on the market against regulatory requirements,
· Communication with notified bodies, authorities and test laboratories.

Other services:

· Risk management process in accordance with ISO 14971,
· Software development in accordance with IEC 62304,
· Verification and efficiency rating,
· Validation of production and testing equipment

Whatever your issues are: We support you as best we can. Talk to us!

Between directive (IVDD) and regulation (IVDR): What needs to be done?

UDI, EUDAMED, software, classification, bottlenecks at the notified bodies: These are just a few of the key words coming from current discussions and, with a view to the coming into force of the IVDR, the greatest obstacles that manufacturers will have to overcome.

What is more, these topics are interdependent, i.e. the results of risk management influence software development, UDI requirements affect the labeling processes and the requirement of post-marketing surveillance must be represented in the QMS, in short: Regulatory is team work.

A five year transitional period sounds a long time. But let's do a quick recalculation together: If you only need 200 working hours for reviewing each of 50 product acts that is already 10.000 hours' working time in total - and so more than an individual can manage in five years.

"The new classification rules and the increased regulation via the notified body associated with them in particular present huge challenges for the manufacturer of IVD. The resulting revision of technical documentation must be well planned and thought out with regard to the time constraints."

Dunja Schildge-Reichmann,
Regulatory Affairs Manager IVD

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