Overview of the biggest changes brought about by the IVDR

Below is a short summary of the most important changes that are coming our way with the new IVDR. Some of these have been discussed before in our newsletters and / or mailings, however, the below article gives another complete overview:

- **Liability:** Insurance coverage for manufacturers will be mandatory. Auth. Reps. will become liable for defective products and will require coverage as well.
- **Classification**: IVDs will now be classified in risk based groups A (low- risk) to D (high public and high patient risk) with seven classification rules. Notified bodies will have to perform conformity assessment on all but class A devices. IVDs that do not fit any of the other classification rules fall into class B and have to be certified by a notified body. This is a major change compared to the IVD Directive, which allows such IVDs to be self-certified.
- **Clinical performance:** Studies will be required to support the CE mark under the IVDR. As a consequence IVD manufacturers will need to produce significantly more clinical evidence. The clinical performance evaluation will include not only the classic clinical performance and analytical performance, but also scientific validity. With this change, the first steps towards manufacturers becoming fully responsible for the clinical utility of their devices are initiated.
- **Conformity assessment routes**: Changes here will have impact on existing quality systems and content of current technical fi les. For example, with the regulation new essential safety and performance requirements (the current Essential Requirements) and a mandatory technical file structure and content will be published.
- **EUDAMED:** This is currently under construction for traceability, registration of devices and publication of information concerning medical devices on the EU market. Manufacturers will need to prepare for and implement Unique Device Identifiers (UDI) for, eventually, all of their devices, although UDI will be implemented in phases based on the risk classes of the products.
- **Post- market surveillance (PMS) and vigilance:** PMS will need to adopt a continuous evaluation and improvement loop.
- **Person responsible for regulatory compliance:** Obligation to have a person responsible for regulatory compliance available within the organization.
- **Supply chain regime:** Will make changes to current distribution and other supply chain agreements necessary. Each actor in the supply chain will have its own regulatory responsibility, a big change from the current situation. Some of the changes include liability of various operators for defective devices, including the authorized representatives.
- **Lab developed tests**: The IVDR will now regulate laboratory- developed tests and diagnostic services offered as an information society service, which will also apply to diagnostic testing services supplied from outside of the EU to EU citizens.
- **Definitions:** Extension of the concept of IVDs to now include ‘lifestyle tests’ by including the elements of ‘indirect medical purpose’ and ‘prediction’ in the definition to include ‘nutrigenetic tests and lifestyle tests’, which are not covered by the current IVD Directive.

In the consolidated final draft of 13 June 2016, the IVDR states a transitional period of five years, with the possibility for certificates to be issued under the old IVD Directive during the transitional period to be valid for a maximum of two years after the end of the transitional period.

Under all circumstances, you will need to invest resources in developing a transition plan for your devices currently on the market. All medical devices currently on the market will need to be (re)certified under the new rules, as no grandfathering has been foreseen in the new Regulations.