Overview of the biggest changes brought about by the MDR

Below is a short summary of the most important changes that are coming our way with the new MDR. 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 become mandatory. Authorized Representatives will be liable for defective products and will need insurance coverage as well.
- **Classification:** Higher risk classifications for, amongst others: Orthopedic implants and medical devices containing nano-materials. Reusable surgical instruments will require Notified Body involvement with regards to their reprocessing procedures.
- **Clinical evidence**: The current text includes more focus on interventional clinical performance studies; key concepts from standards and GCP are being introduced, and ethical consent is detailed. Much stronger wording is in place to have manufacturers provide their own data in the pre-market phase as well as gathered in post-market phase, with much less reliance on equivalence
- **Eudamed database:** Elements such as registration of devices and economic operators, information for the public on products available on the EU market, including a summary of safety and performance are now included. A Unique Device Identification (UDI) system will be embedded, but details have to be defined.
- **Traceability** of medical devices throughout the supply chain has been agreed upon, using suggested methods of UDI, building on the basis laid by the Commission Recommendation 2013/172/EU.
- **Rights & responsibilities** have been defined. These include: rights for users, patients and subjects in clinical studies; and stricter responsibilities for manufacturers, importers and distributors, which will also be applicable to diagnostic services and internet sales. Requirements for appointing people more clearly responsible for regulatory compliance within the manufacturer as well as in the authorized representatives will be in place. And relabeling and repackaging, as well as the regulatory complexity of own brand labeling, have been clarified.
- **Assessment powers** have been increased by including more testing and regular checks on manufacturers, including the unannounced audits. Notified body staff involved in audits now needs to be on a rotation scheme. Also, over time a series of common specifications will be endorsed to support unified high level assessment practices.
- **Supervision of notified bodies:** All notified bodies are being reviewed against the same criteria. This already ongoing change is deemed by many to be one of the two most critical changes in the legislative improvement work.
- **Scope:** For example products manufactured utilizing non-viable human tissues or cells, or their derivatives are now covered. Certain implantable / invasive products without a medical purpose have been added, including a mechanism of reflection on their safety using common specification. And clarification was obtained on products that contain or consist of viable biological substances and on food constituents covered by Regulation (EC) No 178/2002.
- **Better coordination** between member states, as well as a governance system is more or less completely defined. And lastly, **International guidelines** will be **incorporated into EU law.**