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New EU medical device regulation expands product coverage and requires significantly more monitoring

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The European Union will apply new regulations to the medical device sector in May 2020 under the EU Medical Device Regulation (MDR), a sweeping overhaul of the Medical Device Directive, which had been the regulatory standard in Europe since 1992. The MDR significantly tightens and increases pre- and post-market obligations for economic operators (i.e., manufacturers, distributors, importers, suppliers, subcontractors, assemblers and EU Authorized Representatives), establishes a database for all covered devices, and significantly expands the scope of covered devices and substances.

According to Travis Miller, general counsel at Assent Compliance, key objectives of the new regulation are:

- "Stricter lifecycle control of medical devices through enhanced quality management systems and the introduction of a Unique Device Identification (UDI) and a database
- "Introduction of a new risk classification system for *in vitro* diagnostic medical devices
- "Introduction of an implant card containing information about implanted devices for the patient
- "Improved coordination between EU Member States in the fields of vigilance and market surveillance
- "Increased oversight of Notified Bodies"

Medical device supply chains will see a dramatic increase in their regulatory burden through reporting, analysis of components and substances, and training and education in order to comply with the MDR. The EU has published guidance, including a step-by-step process for complying with the new regulations that is available for free.

What's covered?

The MDR covers all medical devices, defined in Article 2.1 as "any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings" for one or more of the following specific medical purposes:

- "diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- "diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- "investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- "providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations"

Article 2 goes into more detail regarding what is and is not a medical device, with the biggest changes being the inclusion of software (which did not exist as a medical device when the Medical Device Directive was drawn up) and devices that were previously considered to be cosmetic or aesthetic, as opposed to medical. Annex XVI provides a list of some of these additions to the list of covered devices:

- "Contact lenses or other items intended to be introduced into or onto the eye.
- "Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.
- "Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.
- "Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.
- "High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.
- "Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain."

Medical devices are classified by type, from "Class I – Non-invasive" to "Class III - Invasive Devices on the Body for a Long Time." All classes except for "Class I – Non-Invasive" require notified body approval.