MDR

Medical Device Regulation (MDR 2017/745)

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Quick Facts about DQS Inc.:

- Formed with a partnership between Underwriters Laboratories Inc. (UL) and DQS (German Registrar of Management Systems). DQS was founded by DGQ (German Society of Quality) and DIN (German Institute of standardization).
- Global presence: 80 offices in 60 countries
- Best in class auditors: over 2,500 competent auditors worldwide
- Large customer base: over 59,000 certifications

The Medical Device Regulation (MDR) will bring substantial changes to the way medical device manufacturers bring their devices to the European market and how they maintain compliance throughout the product's life cycle.

MDR replaces the Medical Device Directive 93/42/EEC (MDD,) which was established in 1998 to harmonize the regulatory requirements for medical devices in the European Union. An amendment came in 2007, which clarified what products were considered medical device, due to continual advancements in technology and development of international initiatives. It became mandatory on March 21, 2010. The new European MDR began a three-year transition period in May 2017.

What is Products are Considered Medical Device?

Medical devices under this directive are defined as any instrument, apparatus, appliance, software, material, or other article intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment, or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or handicap
- Investigation, replacement, or modification of the anatomy or a physiological process control of conception and which does achieve its principal intended action by pharmacological process, immunological or metabolic means but may be assisted in its function by such means

The new regulation also specifies particular types of products that also qualify as medical devices requiring CE Marking.

- Products intended for cleaning, disinfection, and sterilization of medical devices
- Devices for the control and support of conception

DQS USA partners with DQS Medizinprodukte GmbH (DQS Inc.'s holding) to offer MDR.