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QUESTIONS RELATED TO MDR

(1) What is MDR?

a. The Medical Device Regulation (MDR) is a set of regulations in the European Union (EU) that govern the marketing and sale of medical devices.

(2) How does it relate to the FDA?

a. In recent years, there have been efforts to modernize and streamline the FDA's approach to medical device regulation. The United States is moving towards more stringent medical device manufacturing and cleanliness requirements that will mimic the regulations set forth by the EU.

(3) When is MDR coming to USA?

a. It is expected before 2030.

(4) What do we need to do to comply?

a. Determine the correct classification of the medical device you are making based on the MDR's classification rules.
b. Identify the appropriate conformity assessment procedure for the medical device you are making.
c. Conduct a comprehensive clinical evaluation to demonstrate the safety and performance of your device.
d. Establish a robust post-market surveillance system to monitor the safety and performance of your device throughout its lifecycle.
e. Develop and implement a comprehensive Quality Management System (QMS) that aligns with the requirements of the MDR.
f. Assign a Unique Device Identifier (UDI) to your medical device and ensure proper labeling and documentation.
g. Prepare comprehensive technical documentation, including design specifications, manufacturing processes, risk management documentation, labeling, and instructions for use.
h. Conduct internal audits and assessments to ensure ongoing compliance with the MDR requirements.
i. Fulfill post-market obligations, such as incident reporting, field safety corrective actions, and periodic safety update reports (PSURs), as required by the MDR.

(5) How can Omni with Ecoclean help you comply?

a. Our parts washing systems can help you to meet and exceed the Medical Device Regulation (MDR) requirements regarding the cleanliness and sterility of medical devices through technology such as vacuum cleaning and drying for the most complex designs and strictness cleanliness requirement.