MEDICAL DEVICE INNOVATOR CLEARS EU REGULATORY HURDLES

A multinational medical device and equipment company with more than 50,000 employees in 75+ countries needed to meet the new EU Medical Device Regulation to avoid shutting down sales in the European Economic Area.

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THE CHALLENGE:

Complying with the new EU MDR mandate quickly to avoid disruption of business operations in the European Economic Area

The dawn of Brexit brought new challenges and regulations for businesses operating in the European Economic Area (EEA), including the new European Union Medical Device Regulation (EU MDR) that regulates medical device production and distribution. This medical device company faced the reality of complying with these new device and labeling mandates by the end of 2022. Failure to meet the deadline would require the company to discontinue sales and operations in the area, creating a significant impact on a portion of the more than 100 million patients they serve worldwide.

THE SOLUTION:

A holistic approach to compliance with a trusted partner

Meeting these new regulatory and compliance mandates promised to create significant disruption since this work is not a core competency for the organization – they did not have the in-house knowledge or adequate staffing to meet the regulations in a timely manner. They turned to The Judge Group, a trusted partner since 2012, for the strategic guidance and implementation expertise required to meet the EU MDR mandate by the deadline. Judge built a team of quality engineers, mechanical engineers, manufacturing engineers, designers, quality management, and regulatory affairs associates to ensure compliance.

According to MedTech Europe, 54% of medical device companies do not plan to transition their product portfolios to EU MDR, and overall portfolios will decrease by an average of 20%. With Judge's help, this medical device company was able to avoid this significant impact on their business.

THE RESULT:

Meeting the deadline and building a team for long-term consistency

The Judge team worked side-by-side with the medical device company for more than three years to meet the deadline. The partnership ensured that the organization met the EU MDR mandate on time without disruption to its core operations. Based on the project's success, more than 30% of the Judge-sourced team converted to full-time employees at the medical device company, ensuring long-term consistency and an improved ability to meet future regulatory mandates.