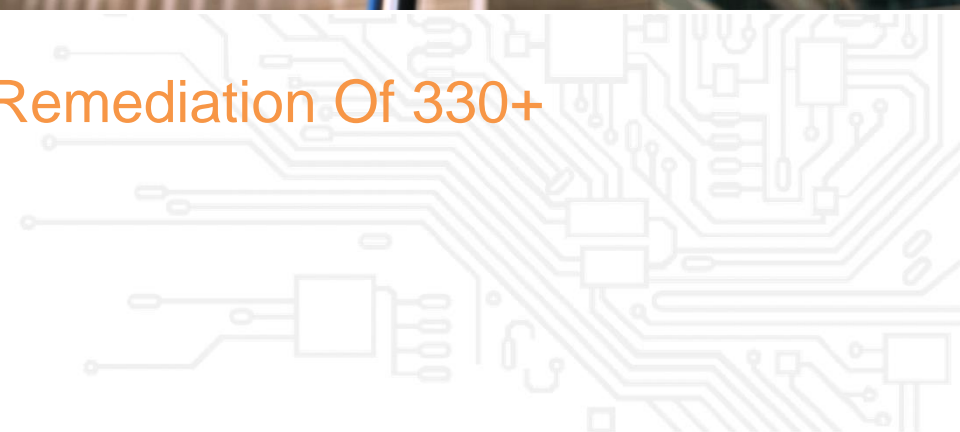




EU MDR Gap Assessment & Remediation Of 330+ Product Systems

CASE STUDY



OPTIMIZED EU MDR TRANSITION PLANNING RESULTING IN 30% REDUCTION IN LEAD TIME

Customer Challenges

Our client is one of the leading orthopedic and surgical medical device manufacturers with about 30,000 products marketed in Europe.

The customer wanted to remediate 330+ product systems consisting of more than 10,000 article numbers as per the new EU Medical Device Regulations (EU MDR) to be able to continue their operations in the EU region.

Scope

- Organization-level assessment for transition preparedness
- Assessment of the current state of the technical files
- Estimation for efforts and budgeting
- 5-weeks of pilot project with 1 product group (42 articles) for optimal planning
- Program planning for the organization-wide transition by the end of 2023



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Approach

Tata Elxsi has been tasked to meet strict deadlines and ensure timely submission on or before the Date of Application (DoA) for EU MDR compliance of the entire product portfolio.

Tata Elxsi performed an organization-level assessment and provided estimation for efforts and budgeting. In addition, the Tata Elxsi team established cross-functional communication within the client organization and its network of contract manufacturers to gather documents and data required for remediation. After successful Class I tech. files certification before the DoA, Tata Elxsi is repeating the transition process for Class IIa, IIb, and III medical devices.

Impact

- Established a Global Engineering Center (GEC) with a team of over 150 cross-functional specialists to perform high volume remediation activities
- Ensured uninterrupted sales of Class I medical devices in Europe
- Reduced lead time by 30% by optimizing transition planning and adopting agile processes in program management
- Established KPIs and pre-defined metrics to measure performance and program health

