TATA ELXSI

# ENSURING UNINTERRUPTED SALES OF LEGACY IVD DEVICES IN THE EU MARKET

CASE STUDY

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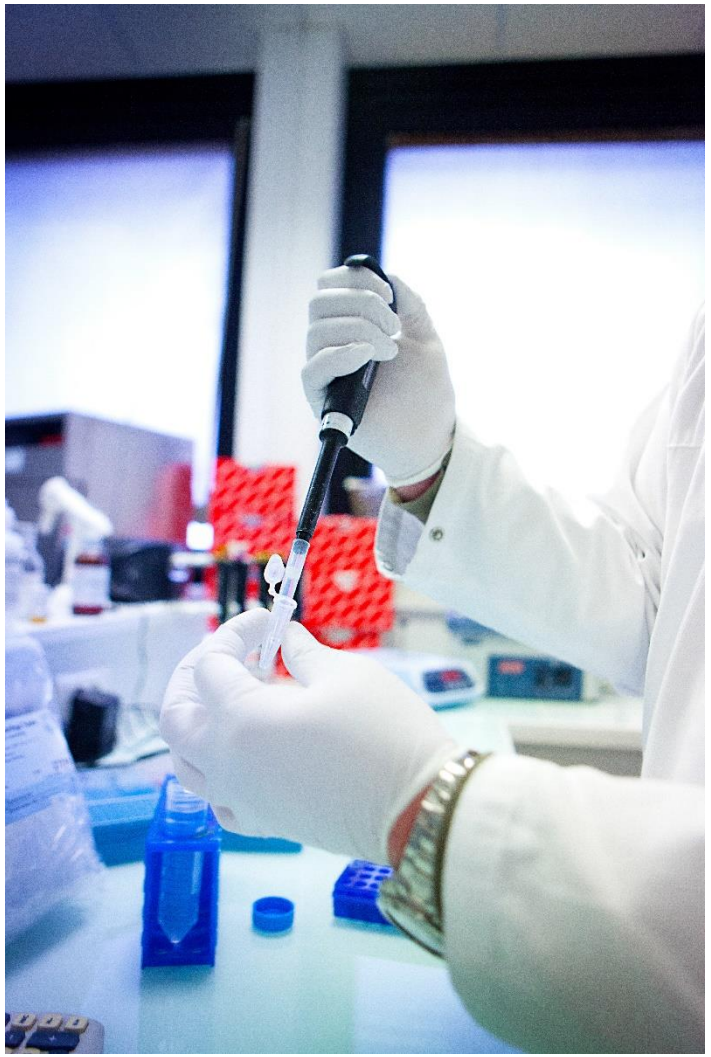
## Customer Challenges

Our client is a US-based manufacturer of diagnostic devices, including molecular biology, immunology, and lateral flow assays.

The customer intended to remediate their legacy self-certified devices as per the new EU In Vitro Diagnostic Regulation (IVDR). As the devices were up-classified under the new regulation, the remediation work involved a massive volume of documentation to ensure successful NB reviews and CE certification.



## Scope

- Product understanding and assessment of the applicable requirements
- Gap assessment to understand the current state of the technical files
- Assessment of the existing raw/processed data, testing reports, and clinical data to check for data sufficiency
- Creation of customized SOPs, templates, and work instructions at the organization level as global procedures
- Project planning and management for execution of the project on anticipated timelines per customer requirements
- Compliance testing and documentation remediation as per the EU IVDR
- Technical file compilation and NB review comments redressal

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## Approach

Tata Elxsi facilitated a cross-functional team of interdisciplinary engineers and regulatory experts to understand the client's entire product portfolio, perform gap assessment and provide estimation for efforts and budgeting.

Our team established a communication channel with the client and their contract manufacturers to collate essential documents and data required for remediation work, especially for the up-classified devices.

We also ensured the successful submission to the Notified Body and addressed the subsequent comments.

## Impact

- Ensured uninterrupted sales of existing IVDs in the European market by receiving the NB approval with minimal or no comments/ observations
- Reduced lead time by 40% by optimizing project planning and adopting agile processes in program management
- Facilitated smooth IVDR transition and allowed the customer to continue their regular R&D activities as planned


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