CYIENT

Case Study

# MDD to MDR Transition & Ultrasound Component Qualification

## Overview

The project aimed at transitioning a Class IIA ultrasound product line from the Medical Device Directive (MDD) to the new EU Medical Device Regulation (MDR) compliance, while simultaneously de-risking single-source components by identifying and qualifying alternative sources. This included checking the Bill of Materials (BoM) for declined, phased-out, and discontinued components, suggesting and qualifying alternates, addressing cost of non-quality issues, and developing a comprehensive verification and testing strategy.

### Customer

Major European Medical Device OEM

### Cyient's Role

Cyient played a pivotal role in ensuring the successful transition of a Class IIA ultrasound product line to EU-MDR compliance and in de-risking single-source components by identifying and qualifying alternatives, while addressing cost of non-quality issues and developing a comprehensive verification and testing strategy.

### Tools Used

Silicon Expert, Fish Bone Analysis, 5-Why Analysis, BoM Scrubbing Tools.

## The Challenges

### MDD to MDR Transition

**Transitioning the ultrasound product line to meet the stringent requirements of EU-MDR, ensuring all compliance documentation and processes were updated and ready for a notified body audit.**

### Ultrasound Component Qualification

**Identifying and qualifying alternative components to replace discontinued or non-compliant ones, ensuring they met form, fit, and function requirements, and addressing field problems and non-quality issues without compromising the device's performance and reliability.**

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## Our Solution

### Framework & Automation

- Developed comprehensive frameworks and templates with automation elements to streamline the compliance and component qualification processes, ensuring efficiency and consistency across future projects.

### MDR Compliance and Audit Preparation

- Detailed preparation for the notified body audit by ensuring all documentation and compliance measures were meticulously aligned with EU-MDR requirements.
- Executed the transition plan across 15 product lines, updating all processes and documentation.

### BoM Scrubbing and Component Qualification

1. **BoM Scrubbing:**

- Separated active and passive parts. Utilized Silicon Expert tools to identify RoHS and REACH compliant alternatives. Created specification comparison sheets for proposed alternates.

2. **Review and Finalization:**

- Conducted internal reviews for form, fit, and function of suggested parts. Facilitated review and finalization by the client.

### Design Impact and Root Cause Analysis

**1. Design Impact Analysis:**

- Created reports for parts requiring design changes and facilitated client review and finalization.

**2. Root Cause Analysis:**

- Analyzed CR documents and field data to understand field problems. Performed RCA using Fish Bone and 5-Why Analysis techniques to identify improvement areas and conducted solution tests.

### PCN Testing and Documentation Update

**Product Change Notification (PCN) Testing:**

- Created PCNs and detailed test plans. Executed module level tests and prepared comprehensive test reports. Updated relevant documentation to reflect changes and test results.

## Achievements

### MDD to MDR Transition

Successfully implemented EU-MDR compliance for Class IIA ultrasound devices across 15 product lines. The frameworks and templates developed have set a standard for future compliance projects, ensuring streamlined and efficient transitions. The project culminated in a successful audit clearance by the notified body.

### Ultrasound Component Qualification

The project led to a robust qualification of alternate components, ensuring the continuity and reliability of the ultrasound product line. Addressing cost of non-quality issues and implementing a rigorous verification and testing strategy significantly improved product quality and reduced risks associated with single-source dependencies.



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