CYIENT

Case Study

# ACCELERATING REGULATORY COMPLIANCE FOR THE MEDTECH INDUSTRY

## Overview

EU regulations for the MedTech industry have been updated to keep pace with latest technologies, fast-paced innovations, AI, ML, and manufacturing techniques and focus on the safety and efficacy of medical devices. This restructuring has impacted almost every medical device manufacturing company, notified bodies, and other stakeholders, creating significant re-certification work and aggressive timelines to be met.

Our CyARC solution is designed to automate the regulatory compliance process for MedTech companies expediting compliance, reducing the document review cycle, and saving compiling efforts. Powered by ChatGPT and supervised rule algorithm, CyARC provides an intelligent regulatory analysis, continuous monitoring of regulations, applicability assessment based on intended use, and automated gap analysis with remediation planning. It offers a rich and unique product matrix overview with information on registrations, certifications, standards, product-related audits, and compliance analysis.

## The Challenge

Our customer, a MedTech company, was investing significant time in drafting, formatting, and reviewing the GSPR checklist—an important document for CE certification.

When working on a DHF remediation project, our customer found gap tracking to be highly tedious, comprising compliance analysis, evidence collection, gap identification, and tracking.

The customer faced situation where regulatory experts were being shared across projects which sometimes delayed design inputs and, in turn, the product development cycle.

## The Cyient Solution

- Cyient identified the automation opportunity and provided an AI-powered digitized GSPR checklist template as part of the CyARC solution. CyARC comes with pre-guided information on methods applied and standards. Create a medical device, apply EU MDR/IVDR template and generate GSPR checklist within seconds.
- CyARC provided a cloud-based web application that seamlessly integrated with the customer's PLM system for evidence recommendation, evidence collection, automatic generation of gaps, and gap tracking.
- The solution provides a scalable regulatory database with document collection from nine countries. With AI-powered regulatory templates, CyARC assesses regulatory requirements against intended use of a medical device, identifies applicable regulatory requirements, and captures justification when not applicable.

## The Results

- Generated over a click, the GSPR checklist report needs no formatting and is capable of saving up to 40% of manual efforts in managing GSPR checklist
- Reviewing gap dashboards and documenting remediations and impact are now really easy with CyARC, with the promise of saving up to 30% of manual effort
- A secured role-based web application with product-level applicability assessment saves the Regulatory Officer significant time spent in gathering regulatory requirements as a design input for various medical devices.

## DESIGNING TOMORROW TOGETHER

Medical Device regulations are undergoing a transition to address the technological advancements and day-to-day innovations in medical device design. CyARC is designed to adapt to these frequent changes in regulations, scale up to the new geographies, and integrate with latest technologies like OpenAI and supervised machine learning. The focus of the solution is to create a solid foundation of a regulatory knowledge database, capable of capturing critical analytical decisions taken by regulatory experts. We provide ways to standardize, customize and apply this regulatory knowledge across products. Our aim is to help our customers to conduct their regulatory compliance business more efficiently and timely.