CYIENT

HELPING MEDTECH OEMS SUCCESSFULLY NAVIGATE EU MDR LANDSCAPE

Reduce risk, ensure timely compliance and secure market position as a manufacturer

Medical device OEMs that market their products in the European Union are grappling with multiple challenges in relation to MDR implementation. While some firms have started the transition and are on the way to successful completion, many others are still figuring out ways to ensure compliance within the May 2020 deadline.

The new regulations require additional focus on device risk classification, technical documentation, clinical evidence, post-market surveillance and transparency of information including new requirements around post-market clinical follow-up.

These additional requirements can be a huge strain on manufacturers' resources and delay in the EU-MDD to EU-MDR transition by the May 2020 which in turn may pose risk to manufacturers' market position.

MDR Compliance Solutions

At Cyient we understand the major challenges faced by OEMs in their MDR implementation journey. Our solutions are specifically designed to help our clients seamlessly navigate through the transition process.

Our MDR solutions include:

- MDD vs MDR gap assessment
- Technical Document Preparation including CER, PMCF, Risk Management and GSPR
- Quality Management System (13485:2016) Compliance
- Verification and Validation Support
- Clinical Development Activities
- UDI Implementation and EUDAMED update

Features of our solution offerings

Strong domain understanding coupled with hands-on experience in MDR implementation has helped us develop best practices for future transition projects. These include:

Structured Content Development

Our team has thoroughly reviewed the new EU-MDR guidelines (GSPR and STED) and has developed reusable templates for Technical Document (Dossier), RMF, CER, PMS and PMCF reports

Language Translation

With a capability for translation to 38 languages, we cater to all the EU countries

Process Automation

We have extensively used XML and AI for automation of processes where applicable

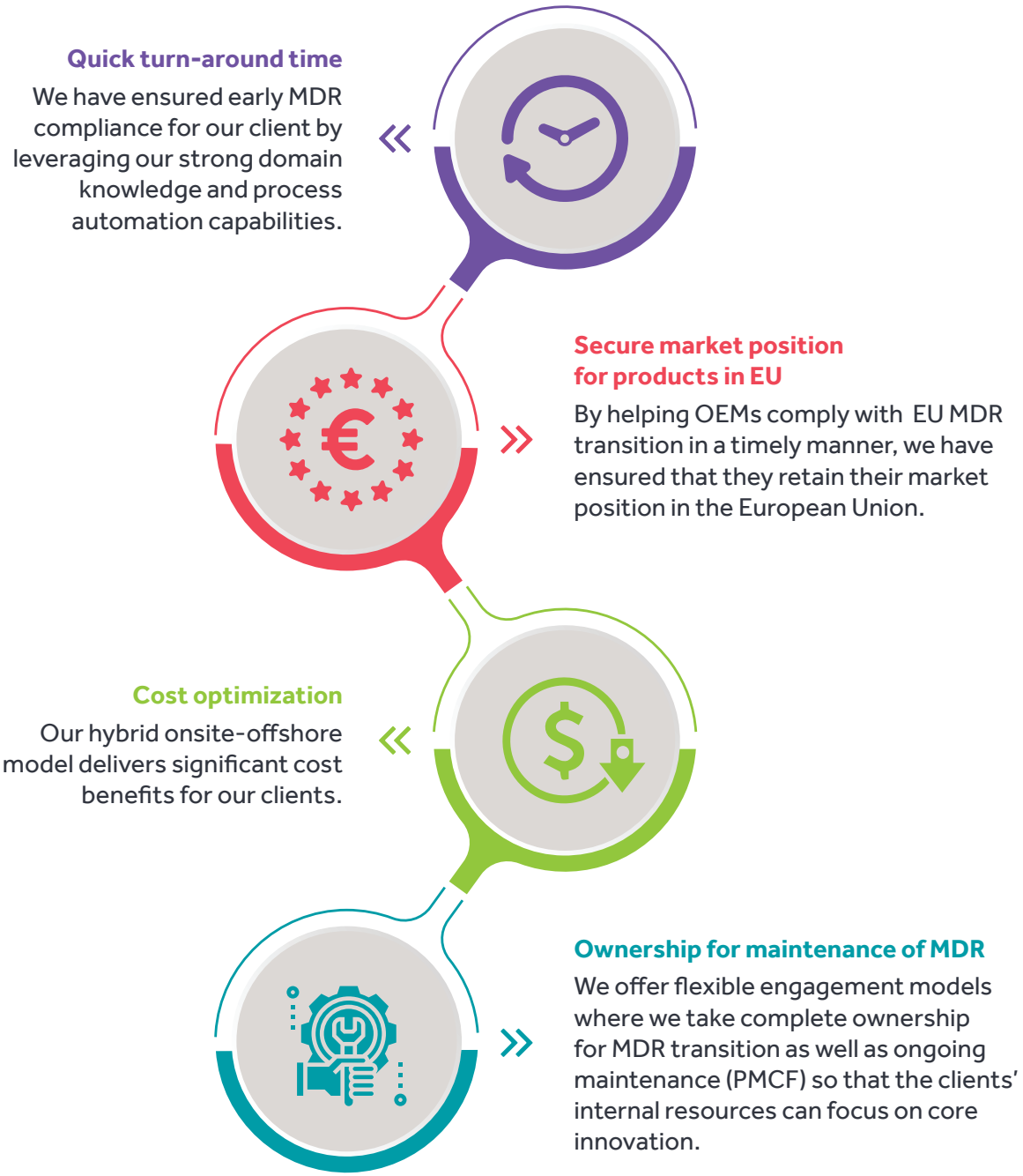
Partner Ecosystem

A robust ecosystem of CROs, labs and testing agencies helps us to offer holistic solutions and be a one-stop-shop for our clients

Business Benefits

Our clients have reaped multiple benefits by collaborating with us for EU MDR transition.

The top reasons to partner with Cyient for MDR compliance solutions are:



Quick turn-around time

We have ensured early MDR compliance for our client by leveraging our strong domain knowledge and process automation capabilities.

Secure market position for products in EU

By helping OEMs comply with EU MDR transition in a timely manner, we have ensured that they retain their market position in the European Union.

Cost optimization

Our hybrid onsite-offshore model delivers significant cost benefits for our clients.

Ownership for maintenance of MDR

We offer flexible engagement models where we take complete ownership for MDR transition as well as ongoing maintenance (PMCF) so that the clients' internal resources can focus on core innovation.

Success Story

Ownership of MDR transition and sustenance for the highest revenue generating ultrasound platform of a top-5 diagnostic imaging company

The Problem: Our longstanding client, a leading Europe based diagnostic imaging company, wanted to begin their MDR transition for a Class IIa ultrasound machine. As this was a pilot MDR project, the client team did not have reliable references.

The Solution: Cyient began with reviewing the existing documents and generating a gap-analysis report. Based on the gap analysis, the team developed the EU-MDR compliant technical document template. One of the most critical elements of the MDR was V&V section development which in turn required a report on biocompatibility, EMC, DQT, and SW validation. Each of these parameters required analysis and summary of over 80 pages. Our team successfully developed EU-MDR technical document template, structured summaries related to EU-MDR technical documentation, full length technical documents (dossiers), Clinical Evaluation Reports (CERs), PMS and PMCF plan documents. We also reviewed GSPR and STED guidelines, prepared EUDAMED templates supporting in EU MDR regulatory submission(s).

Impact: Cyient delivered an extensive 200-page technical documentation (dossier) that was well-received by the Notified Body Auditor. The exercise helped client in ensuring MDR compliance ahead of time for one of its highest revenue generating product-lines. For Cyient, the success of this project brought additional projects for MDR compliance and ongoing maintenance.

Cyient was hugely appreciated for its contribution in the EU MDR transition Here are some of the testimonials in our clients' own words:

"Greatly appreciate the effort from all the individuals who contributed in their own way for audit preparedness and successful execution"

- Senior Regulatory Affairs Specialist

"Approximately 200 pages of Technical Documentation received a very thorough review and also received nice compliments from the Notified Body reviewer:

- **Well-structured and clearly outlined content**
- **Helped clearly understand the scope of the CE Marked devices**
- **Well documented Classification Rationale for the medical devices**
- **Essential Requirements Checklist was easy to follow"**

- Notified body (BSi) and Director, Regulatory Affairs

The Cyient Advantage

- In-depth knowledge of EU-MDR to ensure timely transition to the new regulation
- Experienced resources with multiple years of experience in medical device regulatory space
- A hybrid onsite-offshore model ensures cost-savings for the client
- Reusable templates and automation tools help faster time-to-compliance

About Cyient

Cyient (Estd: 1991, NSE: CYIENT) is a global engineering and technology solutions company. As a Design, Build, and Maintain partner, for leading organizations worldwide, we take solution ownership across the value chain to help clients focus on their core, innovate, and stay ahead of the curve. We leverage digital technologies, advanced analytics capabilities, and our domain knowledge and technical expertise, to solve complex business problems.

With over 15,000 employees in 20 countries, we partner with clients to operate as part of their extended team in ways that best suit their organization's culture and requirements. Our industry focus includes aerospace and defense, healthcare, telecommunications, rail transportation, semiconductor, geospatial, industrial, and energy.

For more information, please visit
www.cyient.com

Contact Us

North America Headquarters
Cyient, Inc.
99 East River Drive
5th Floor
East Hartford, CT 06108
USA
T: +1 860 528 5430
F: +1 860 528 5873

Europe, Middle East, and Africa Headquarters
Cyient Europe Ltd.
Apex, Forbury Road,
Reading
RG1 1AX
UK
T: +44 118 3043720

Asia Pacific Headquarters
Cyient Limited
Level 1, 350 Collins Street
Melbourne, Victoria, 3000
Australia
T: +61 3 8605 4815
F: +61 3 8601 1180

Global Headquarters
Cyient Limited
Plot No. 11
Software Units Layout
Infocity, Madhapur
Hyderabad - 500081
India
T: +91 40 6764 1000
F: +91 40 2311 0352

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