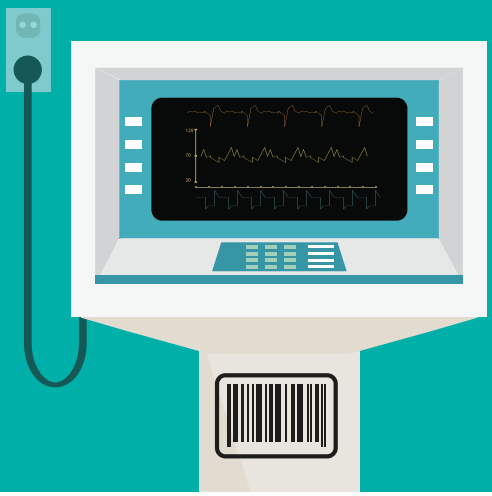
Are you prepared for EU MDR?

Call on KPMG LLP's experienced professionals to assist in your readiness for the latest medical device requirements



The EU Medical Device Regulation (MDR) was published on May 5, 2017. MDR is replacing the EU's current Medical Device Directive (93/42/EEC) and Active Implantable Medical Devices Directive (90/385/EEC) with a transitional period expiring on May 26, 2021.

Strategic Insights	
Functions Impacted	**Opportunities**
R&D Clinical	Leverage MEDDEV 2.7/1 rev 4 compliance
Regulatory Affairs	Consolidate design center documentation & increase IT capabilities during conversion of technical files to the STeD format
Data Governance	Data change control, data integrity & governance during ongoing maintenance between technical documents and Eudamed"
Medical Safety	Develop strategy for and author PSUR and PMSP documentation over the entirety of a device's lifecycle
Manufacturing & Operations	Improve end-to-end label change process and limit future rework/ potential product obsolescence
Quality Management Systems	Develop a training strategy throughout implementation of new/ updated company procedures

Key Changes

- Increased Control for National Regulators
- Interaction Changes with Notified Bodies
- New / Updated Classification Rules
- New EU Database on Devices (Eudamed)
- Better Traceability of Medical Devices (UDI)
- New Clinical Evidence & Safety Requirements
- Increased Periodic Safety Update and Vigilance Reporting Requirements

EU MDR Time Line

2020

April – Due to the effects of the COVID-19 Pandemic, commission decides to extend the date of application one year from May 26, 2020 to May 26, 2021

2021

May 26, 2021 – End of MDR transition period (i.e. must comply and be certified to EU MDR requirements or have plan in place to utilize transitional provisions under Article 120)

2024

May 26, 2024 – End of MDR transitional provisions period (i.e. all MDD certificates will expire)

KPMG Value Proposition

Assess Current State	Implementation & Remediation (as needed)	Lifecycle Management and Sustainability	Monitoring/ Improvement
Assess current state readiness against MDR requirements	Execute remediation activities to address deficiencies and gaps	Develop and implement lifecycle management program to ensure ongoing requirements defined by MDR are met	Leverage lessons learned to improve processes for future updates

Relevant Experience

- 10+ gap assessments completed
- Established MDR program governance model
- Conducted pilot to verify implementation plan
- Determined sustainable model to update technical files to STeD

KPMG Accelerators

- MDR audit checklist
- Governance structure
- Technical data preparedness checklist
- Economic Operators process model
- Established resource model
- Sustainability strategy & operating model

Value Beyond Compliance

- Improve business processes
- Accelerate organizational maturity
- Implement technology solutions
- Leverage off-shore resources
- Provide industry benchmarks

Our services

Service	What we do	What you get
MDR Readiness Checklist	Assess the remaining gaps and areas of risk prior to the May 2021 DoA	Understanding of where you stand against the MDR requirements as May 2021 approaches
Remediation Support & Audit Response	Remediate existing gaps in technical documentation and prepare for certification audits	Remediated technical documentation & strategy for compliance
Sustainability Roadmap	Define the processes and procedures impacted by lifecycle management requirements	MDR Sustainability roadmap and resourcing model
2020+ Resource and Project Planning	Develop the plan including resource loading, timelines, and dependencies	Timeline and resources required

Contact us

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KPMG insight

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