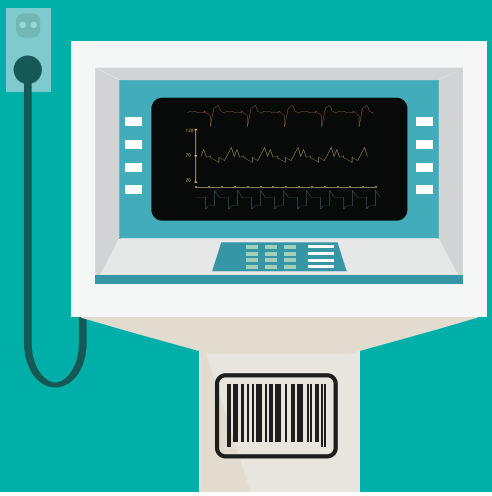
Are you prepared for EU MDR and IVDR?



Call on KPMG's experienced professionals to guide you in your journey toward compliance

The EU Medical Device Regulation (MDR) & In Vitro Diagnostics Regulation (IVDR) were published on 5th May 2017. MDR will replace the EU's current Medical Device Directive (93/42/EEC) and Active Implantable Medical Devices Directive (90/385/EEC) with a 3 year transitional period. IVDR will replace the EU's current In Vitro Diagnostic Device Directive (98/79/EC) with a 5 year transitional period.

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	Leverage UDI-DI assignments to improve device lifecycle management
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 and IVDR Time Line

2017

- Law published on Friday, 5/5
- EU MDR & IVDR takes effect 5/26
- Certificates can be issued according to MDR
  MDR from 5/26/17 to 5/26/2020
  IVDR from 5/26/17 to 5/26/2022

2018

- MDR/IVDR certificates first available Summer 2018 (projected date)

2020

- MDR – End or transistion period 5/26/20 (i.e. must comply and be certified to EU MDR requirements

2022

- IVDR – End or transistion period 5/26/22 (i.e. must comply and be certified to IVDR requirements

The KPMG approach

Impact/ Gap Assessment	Pilot (as needed)	Implementation/ Remediation	Monitoring/ Improvement
Pinpoint key gaps & remediation needs to develop compliance roadmap	Process chosen products through entire remediation lifecycle	Execute comprehensive remediation activities for complete portfolio	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

- Business requirements
- Governance structure
- Cross-functional processes outlined
- Known interdependencies
- Established resource model
- Financial impact baseline

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
Current State Gap Assessment	Highlight the areas of significant risk to the organization to achieve compliance	Understanding of where you stand on compliance journey
Business Requirements Development	Review known requirements and determine how they apply to your company	Blue print for the work needed to be done for compliance
Program Governance Set Up	Identify stakeholders required, meetings required, and build tools & templates	Project established to manage the multi-year effort
2018+ 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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