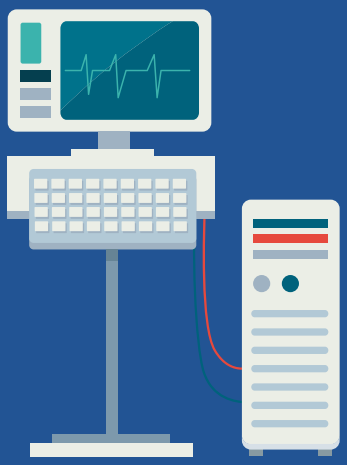
Are you prepared for EU MDR?



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

The EU Medical Device Regulation (MDR) was 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.

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	We can provide apps for: education / training, process / SOP management (R&D, Production), patient infomation / leaflets, expriy dates, issue recording. probably also others…

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

2017
- Law published on Friday, 5 / 5
- EU MDR takes effect 5 / 26
- Certificates can be issued according to MDR from 5 / 26 / 17 to 5 / 26 / 2020

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

2019

2020
- MDR – End or transistion period 5 / 26 / 20 (i.e. must comply and be certified to EU MDR requirements

The KPMG approach

Impact / Gap Assessment	Pilot (as needed)	Implementation / Remediation	Monitoring / Improvement
Certificates can be issued according to MDR from 5 / 26 / 17 to 5 / 26 / 2020	Process chosen products through entire remediation lifecycle	Execute comprehensive remediation activities for complete portfolio	Leverage lessons learned to improve processes for future updates / monitoring app

Relevant Experience
- Globally 10+ gap assessments completed
- Established MDR program governance model
- Determined sustainable model to update technical files to STeD

KPMG Accelerators
- Understanding of business requirements
- Proven Governance structure
- Cross-functional processes outlined
- Known interdependencies
- Financial impact baseline

Value Beyond Compliance
- Improve business process efficiency
- Implement technology solutions
- Successful partnerships
- Provide industry benchmarks
- Digital / Mobile tools

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, evaluate / build tools & templates	Project established to manage the multi-year effort
2018+ Resource and Project Planning / Tool Support	Develop the plan including resource loading, timelines, and dependencies / Build digital and mobile tools	Timeline and resources required

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KPMG insight

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