VALIDANT

EU MDR and IVDR Compliance

Are you prepared for EU MDR compliance?

Confidently answer that question with Validant.

No longer directives, but laws that enforce penalties, the European Union Medical Device Regulation (EU MDR) and In Vitro Diagnostic Regulation (EU IVDR) will increase the scope and stringency of compliance dramatically.

Did you know?

Validant's global network includes **3,500+ strategists, operators, and regulators.**

Bring in the Experts:

Accelerate EU MDR/IVDR Compliance Readiness with Validant

Validant's team has helped multiple medical device clients, from start-ups to top 30 leaders, implement a sustainable approach to EU MDR and IVDR compliance.

Whether you need a turnkey solution to develop and execute a complete, compliant regulatory strategy or additional expertise to tackle specific complexities like periodic safety update reports (PSURs) or clinical evaluation reports (CERs), Validant will deliver the expert resources you need, when and where you need them.

Our priority is on both rapid execution and empowering your internal quality and regulatory departments to sustain compliant processes.

1.884.VALIDANT | info@validant.com | www.validant.com

Our services include:

Gap Assessment

Review of QMS and technical documentation to assess compliance with EU MDR/IVDR.

Pilot Program

Remediation of select files to estimate cost, duration, and improvement impact of full-scale EU MDR/IVDR compliance plan.

Notified Body Submission & Response

Managing file submissions to obtain CE marking and ISO 13845 certificates.

Compliance Plan Execution

Phased implementation including project management, process/ procedure updates, template creation, and record creation/remediation.

Ongoing Maintenance

File maintenance will be much more complex under MDR, and Validant offers the option to contract our team to work alongside your Regulatory Affairs department to maintain your files in perpetuity.

Training & Knowledge Transfer

For leadership and targeted roles throughout the organization to ensure sustainable compliance.

New regulations are coming, but Validant is ready to help you **establish more effective, sustainable processes** that have positive business impact beyond just regulatory obligation.

Discuss your EU MDR and IVDR compliance needs with Validant today:

1.884.VALIDANT | info@validant.com | www.validant.com

Offices in: San Francisco, CA | Durham, NC | Boston, MA | Cork, Ireland

VALIDANT