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VERISTAT

Ease Your Medical Device and *In Vitro* Diagnostic Regulatory Journey in Europe

Successfully Manage Regulatory Complexity in an Evolving World

We understand how challenging it is to keep up in an ever-changing European medical device (MD) and *in vitro* diagnostic (IVD) regulatory landscape. The experienced professionals at Veristat deliver the certainty you need to ensure your product's regulatory needs are addressed comprehensively and proficiently throughout your product's lifecycle.

And as EU regulations evolve, we'll make sure you satisfy the changing requirements. Work with our regulatory experts and project managers from concept feasibility to post-market surveillance, or select the specific set of services that complement your internal capabilities.

An Unequalled Commitment to Compliance and Quality

> Expert guidance transitioning clients from MDD to MDR and from IVDD to IVDR

> Successfully navigate the impact of the MDR deferral on MAA of combination products

> Specialized support to address borderline classification designations for MDs and IVDs

> Expert regulatory guidance in product development under MDR or IVDR

Tailored EU MD/IVD Regulatory Solutions

Strategic Analysis

> Regulatory road map
  - Activity planning from device conception to CE mark designation
  - CE mark designation risk/benefit scenario analyses
  - GSPR analysis
> Regulatory development gap analysis
  - Full analysis of available data from the MD or IVD
  - Detailed next steps planning mapped to future milestones

Regulatory Operations

> Classification analysis
> Preparation of critical documents for CE mark designation
> Technical documentation compilation
> Quality-related processes including risk management plans (RMPs)

Clinical Investigation/ Performance Investigations

> Statistical planning and analysis support
> Data management

Combination Products

> Integral drug-device combinations (DDCs)
> Non-integral DDCs

Other Services

> Interactions with Notified Bodies
> Interactions with the National Agencies

Be Certain in the Ever-Changing European MD/IVD Landscape

Veristat's team of highly dedicated and experienced regulatory professionals ensures the fulfillment of every aspect of your regulatory requirements, from strategy-setting to submissions and approvals and post-approval maintenance.

Contact Veristat Today

Learn more about our MD/IVD expertise.

www.veristat.com/regulatory-medical-device-ivd