IVDR Consultancy Expanded Globally by I3CGLOBAL for In Vitro Diagnostic Manufacturers

IVDR Consultancy by I3CGLOBAL expands to help global IVD manufacturers achieve CE Marking compliance under EU IVDR 2017/746 efficiently.

IVDR Consultants for CE Marking

I3CGlobal

NEW DELHI, DELHI, INDIA, October 21, 2025 /EINPresswire.com/ -- I3CGLOBAL, a global leader in medical device and in vitro diagnostic (IVD) regulatory consulting, announces the enhancement of its IVDR CE Marking consultancy services to support manufacturers worldwide in navigating complex regulatory frameworks. This expansion reinforces I3CGLOBAL's commitment to helping companies achieve IVD CE Marking efficiently while ensuring full compliance with the latest IVDR regulations.

"Our team at I3CGLOBAL is dedicated to guiding IVD manufacturers through the evolving regulatory landscape," said Soio George, Project Head at I3CGLOBAL. "With our strengthened IVDR CE Marking consultancy, we provide comprehensive support from technical documentation and risk assessment to Notified Body coordination, helping IVD manufacturers meet regulatory requirements and accelerate EU market entry. We also offer expert IVDR performance study planning and guidance, one of the most challenging requirements for manufacturers, ensuring that clinical evidence meets regulatory expectations. To further strengthen our services, we have established a collaboration with IQZYME Medtech Private Limited, and their core IVD technical experts Mr. Sinto Paulose, Mrs. Salma Siyavudeen, and Dr. Chandranand P.S, bringing additional expertise to support manufacturers in achieving IVDR CE Marking compliance."

I3CGLOBAL's services include:

- Preparation and review of IVDR CE Marking technical documentation
- Guidance on IVDR Regulation compliance and Post-Market Surveillance planning
- Expert support for IVDR performance study planning
- Coordination with Notified Bodies for certification processes
- Consultancy from experienced IVDR consultants across multiple device classes

By leveraging its deep expertise and strategic collaborations, I3CGLOBAL ensures that manufacturers can confidently meet both EU regulatory requirements and international market standards.

Why Technically Strong IVDR Consultants Are Essential for CE Marking Success

Under IVDR (EU) 2017/746, the Performance Evaluation (PE) is one of the most technically demanding parts of the IVDR CE Marking process for IVD devices. It is not merely a documentation step but a scientific validation demonstrating that an IVD performs as intended. Strong technical expertise is essential to interpret biological assay principles, analytical performance metrics such as sensitivity and specificity, and clinical performance data. Only experienced IVDR consultants with deep scientific knowledge can identify data gaps, design corrective studies, and provide the justifications required by Notified Body reviewers.

Technically strong IVDR consultants bring cross-disciplinary experience across molecular biology, biochemistry, biomedical engineering, and regulatory science. Their ability to design, analyze, and interpret analytical and clinical performance studies ensures that laboratory evidence aligns with Annex XIII of the IVDR and MDCG guidance. By translating complex experimental data into a compliant and defensible Performance Evaluation Report (PER), these experts bridge the gap between laboratory science and regulatory compliance reducing the risk of rejection or costly re-submissions.

Engaging a technically experienced IVDR consulting team not only ensures compliance but also significantly reduces time and cost for manufacturers seeking IVD CE Marking. Expert consultants can anticipate Notified Body expectations, streamline data collection, and prevent errors that often delay certification. Their deep technical insight and regulatory precision enable faster approvals, smoother audits, and a more efficient path to CE certification—helping IVD manufacturers enter the EU market with confidence and compliance.

About I3CGLOBAL

Founded in 1999, I3CGLOBAL has successfully supported over 500 medical devices and IVD CE Mark approvals worldwide, along with more than 120 FDA 510(k) clearances. The company offers end-to-end regulatory compliance consulting, including CE Marking, FDA submissions, GMP support, and clinical evaluation services for medical devices and IVDs.

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