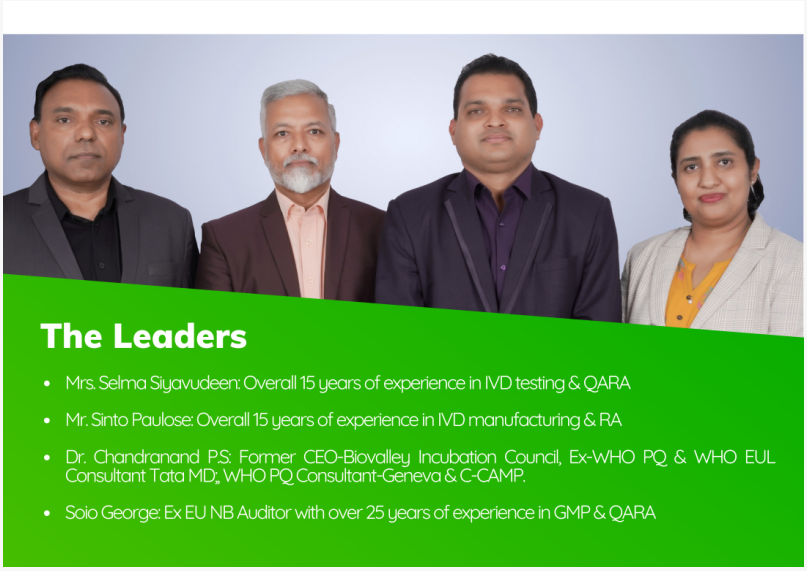
IVDR CE Certification: Low Manufacturer Awareness as Self-Declared Devices Now Require Notified Body Oversight

IVDD Self-Declared Devices Now Require Notified Body Assessment Under IVDR



IVDR Consultants for CE Marking

I3CGlobal

NEW DELHI, INDIA, December 11, 2025 /EINPresswire.com/ -- I3CGLOBAL, a leading global regulatory compliance consulting organization, has issued an urgent industry advisory highlighting the low level of awareness among IVD manufacturers regarding the mandatory compliance requirements under the EU In Vitro Diagnostic Regulation (IVDR) 2017/746 especially among companies whose devices were previously self-declared under IVDD and now fall under Class B and C requiring Notified Body involvement for the first time.

Under the former IVDD (98/79/EC), nearly 80–90% of IVDs were self-certified, with manufacturers placing products on the EU market without Notified Body oversight. The IVDR fundamentally changes this landscape. Many devices previously self-declared under IVDD including a large portion of Class B devices and few Class C are now subject to full Notified Body conformity assessment, including:

Performance Evaluation (Scientific Validity, Analytical & Clinical Performance), robust Technical Documentation aligned with Annex II & III, PMS and PMPF planning and IVDR-compliant Quality Management System. This has resulted in a massive increase in certification workload, both for manufacturers and Notified Bodies.

According to I3CGLOBAL's internal survey of 1800 + manufacturers in Asia, more than 70% are not aware their self-declared IVDD devices will need Notified Body review. Over 60% have not yet begun preparing IVDR compliant technical files. Only 15% understand the IVDR transition deadlines and conditions. Most underestimate the effort required for performance evaluation and PMS/PMPF systems

"The biggest risk today is not the regulation it is the lack of awareness among manufacturers," said Mrs. Asha Johnson, Senior Manager at I3CGLOBAL. "Many companies mistakenly assume their IVDD documents can be reused. In reality, IVDR requires 5 to 10 times more evidence, structure, and data."

Critical Transition Deadlines for IVDR Compliance

I3CGLOBAL also highlighted the official IVDR transition timeline, which is often misunderstood by manufacturers. Missing any of these milestones will result in immediate loss of market access.

Class C Self-Certified 26 May 2025 26 May 2026 26 Sep 2026 31 Dec 2028
Class B / A (Sterile) Self-Declared 26 May 2025 26 May 2027 26 Sep 2027 31 Dec 2029

The longest transition (ending 31 December 2029) applies to Class B self-declared devices, but only if manufacturers meet the pre-conditions—most importantly. I3CGLOBAL warns that Notified Body capacity is already tightening, and delay will force many companies into certification bottlenecks.

I3CGLOBAL recommends that manufacturers, begin technical file development immediately, especially performance evaluation and start preliminary discussions with Notified Bodies early. Avoid last-minute submissions that may lead to review delays or rejection

About I3CGLOBAL

I3CGLOBAL is a global regulatory consulting leader with over 25 years of experience, supporting manufacturers in IVDR CE marking, MDR compliance, FDA 510(k), QMSR, ISO 13485, and global market approvals. With a team of more than 100 regulatory experts, the company has successfully delivered 180+ FDA 510(k) clearances and 1500+ CE approvals across medical and in vitro diagnostic devices.

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