ABL Diagnostics Confirms BSI Partnership for IVDR Transition and Long-Term Availability of its CE-IVD Medical Devices

Expanded GRC and R&D capabilities plus an enhanced QMS accelerate IVDR-compliant innovation and prepare for FDA QMSR and global markets.

WOIPPY, FRANCE, July 16, 2026 /EINPresswire.com/ -- ABL Diagnostics (Euronext Paris – ISIN: FR001400AHX6 – Ticker: ABLD), a leading company in the development of molecular biology assays and software for infectious diseases, today announced a significant milestone in its transition to the European In Vitro Diagnostic Medical Device Regulation (IVDR) (EU) 2017/746.

In full coordination with its parent company, which acts as the legal manufacturer of the CE-IVD marked products, ABL Diagnostics confirms a successful engagement with BSI, a premier global Notified Body. This formal partnership guarantees that the company is fully aligned with the expected regulatory timelines, ensuring a seamless transition of its entire portfolio—encompassing both wet-lab assays and software as a medical device (SaMD)—to the stringent new European standards.

The IVDR introduces a rigorous risk-based classification system and heightened scrutiny for all diagnostic technologies. Recognizing the complexity of this shift, the European Union established extended transitional provisions to guarantee the continued supply of essential medical technologies. Having met all preliminary requirements, including the implementation of an upgraded Quality Management System (QMS), which is already ISO 13485 certified, and timely application submissions to BSI, ABL Diagnostics is tracking precisely to the official regulatory timelines:
- Class C Medical Devices (Transition Deadline: December 31, 2028): The majority of ABL Diagnostics' portfolio falls under this category. This includes the company's flagship DeepChek® disease-genotyping assays as well as its specialized ViroScore and DeepChek® pieces of software.
- Class B Medical Devices (Transition Deadline: December 31, 2029): This category covers a select range of the company's offerings, specifically the UltraGene qPCR product line, which will complete its transition seamlessly by the 2029 deadline.

Transitioning to the IVDR demands an unprecedented level of clinical evidence, post-market surveillance, and technical documentation. To manage this substantial technical workload and ensure flawless execution, ABL and ABL Diagnostics have strategically expanded the workforce.

The companies have recently onboarded new, highly specialized experts within its Governance, Risk, and Compliance (GRC) and Research & Development (R&D) teams. This targeted expansion of human capital directly supports the regulatory load while reinforcing companies' capacity for ongoing clinical and technological innovation.

Through this proactive regulatory roadmap and operational scale-up, ABL Diagnostics, in charge of commercialization of the products, reassures its global network of clinical laboratories, hospitals, and healthcare professionals that all current CE-IVD marked innovations will remain available on the market at least until the end of the transition period.

"Patient safety and diagnostic reliability drive everything we do," said Ronan BOULME, GRC Director and PRRC for the ABL Group. "Embracing the rigorous IVDR framework aligns perfectly with our internal commitment to delivering the highest caliber of clinically validated tools. This milestone is the culmination of a steady, continuous effort initiated back in 2020 with the launch of our very first CE-IVD assay. By securing our partnership with BSI, aligning closely with ABL Luxembourg, our parent company and legal manufacturer, and expanding our internal GRC and R&D capabilities, we are proud to guarantee our partners a seamless transition and the long-term availability of our comprehensive in vitro diagnostics (IVD) medical devices, the legacy and the new ones."

Looking beyond the transition of the existing portfolio, ABL Diagnostics is leveraging its upgraded regulatory framework to accelerate its pipeline of next-generation diagnostic technologies.

"Securing our legacy products is only the first step; our true focus is on continuous innovation," Dr. Chalom SAYADA (CEO) continued. "I have explicitly tasked our R&D and GRC teams to channel this momentum into bringing brand-new DeepChek® and UltraGene innovations to market. By embedding rigorous IVDR-compliant design controls into our development process from day one, we ensure that our future molecular assays and software medical devices are built to the world's highest regulatory standards from inception, accelerating their path to the clinicians and patients who need them."

By anchoring its upgraded Quality Management System to the internationally recognized ISO 13485:2016 standard, ABL Diagnostics is structurally positioned for global commercial expansion. This robust framework ensures that the company's manufacturing and design controls seamlessly align with international expectations outside the European Union. Specifically, this includes readiness for the U.S. Food and Drug Administration's Quality

Management System Regulation (QMSR), as well as regulatory frameworks across major territories in the Asia-Pacific (APAC) and Latin American (LATAM) regions, facilitating smooth registrations for future international product launches.
ABL Diagnostics will continue to keep its customers and stakeholders informed as individual products within its infectious disease portfolio receive their official IVDR certificates ahead of the

regulatory deadlines.

About ABL Diagnostics (ABLD)
ABL Diagnostics (ABLD) is an international company that specializes in innovative molecular biology tests and global solutions for its customers:
- Molecular polymerase chain reaction (PCR) detection – UltraGene, and
- Genotyping by DNA sequencing – DeepChek®.

ABL Diagnostics markets its entire product range globally through its own sales team and a network of exclusive distributors active on all continents. ABL Diagnostics' customers are academic clinical pathology laboratories, private reference laboratories and researchers willing to implement innovative and robust microbiological content in constant expansion.

ABL Diagnostics has been marketing the products and services of its sister company CDL Pharma since the second half of 2025 through an intra-group strategy agreement.

Integrated Solutions
- Real-time syndromic PCR tests
- Nadis® – Patient Medical Record used in more than 200 hospitals in France for the management of HIV and hepatitis.
- MediaChek® – Clinical Sample Collection Kits.

ABL Diagnostics, headquartered in Woippy, is a public limited company listed on compartment B of the regulated market of Euronext in Paris (Euronext: ABLD – ISIN: FR001400AHX6). These molecular biology products generate recurring revenues and cover one of the largest portfolios of applications in microbiology.

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