

Abionic Receives IVDR Certification for Its Predictive Ultra-Rapid Sepsis Test



- BSI certification agency has granted Abionic's abioSCOPE® device and PSP test the IVDR certification for in-vitro diagnostics.
- This certification complies with Europe's new In-vitro Diagnostic Regulation (IVDR), and will be required for products sold within the EU from May 2022 onward. A transitional regulation allows established, non-IVDR-certified products to be sold and used if they entered the EU before May 2022.
- Pancreatic Stone Protein (PSP) on the abioSCOPE® is the earliest marker of sepsis, allowing for its identification up to 72 hours before the standard of care in 5 minutes.
- The newly IVDR certified PSP test is particularly useful for guiding physicians in the decision to start or modify antibiotic treatment.

Abionic SA, a developer of disruptive nanotechnology-based diagnostic solutions, has announced that its Pancreatic Stone Protein (PSP) test on the abioSCOPE® has been certified by BSI certification agency as complying with the European In-vitro Diagnostic Regulation (IVDR), EU 2017/746. This certification granted by notified bodies like BSI is required for in-vitro diagnostics to continue being sold in the European Union. The IVDR's extensive requirements were adopted by the European Parliament in 2017 and must now be implemented by May 26, 2022.

IVDR becomes mandatory as of May 26, 2022. There are also transitional rules that will allow well-established instruments that have not been IVDR certified, but that entered the EU before, to still be sold until 2025. Depending on their shelf life, they may also be used after 2025. Abionic has been preparing for IVDR compliance since 2019, and chose BSI, a reputable notified body that was authorized to perform this certification process.

"As part of its ongoing commitment to meeting the highest standards to ensure patient safety and meet customer needs, Abionic is proud to have achieved the required IVDR certification for its class C product," stated Dr. Iwan Märki, CTO of Abionic.

Improving the management of antibiotic administration

Antibiotics are medicines that are used to prevent and treat bacterial infections, which have revolutionized healthcare since the 1930s and have been paramount in saving millions of lives. However, a systematic overuse and misuse of antibiotics is leading to a concerning increase in the number of antibiotic resistant bacteria, which are becoming harder to treat and causing more severe and fatal infections. International and national healthcare organizations such as the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC) have identified antibiotic resistance as one of the biggest threats to global health today. The over-prescription of antibiotics by healthcare workers is a key contributing factor leading to resistance, with a direct relationship between antibiotic consumption and the emergence and dissemination of resistant bacteria strains (Nature. 2013;495(7440):141). Studies have shown that antibiotic therapy is incorrectly prescribed in as many as 60% of patients receiving hospital care and is likely to be even higher outside this environment (Luyt et al., Critical Care, 2014). Aside from contributing to resistance, inappropriate antibiotic use may lead to increased mortality and severe disease, increased healthcare costs, increased lengths of stay in hospital and the need for more complex treatments leading to a higher risk for adverse effects and unwanted drug interactions.

Dr. Samir Vora, infectious disease physician, Geneva, Switzerland, commented: "The PSP assay has the potential to help the physician decide whether or not to start antibiotic therapy, and thus contribute to reducing the two major public health problems of sepsis and antimicrobial resistance."

Two years after the commercial launch of its sepsis test, Abionic's expansion is reaching a global scale. With over 50 markets already covered, Abionic's next big step is the U.S. where sepsis represents the single largest cost to the healthcare system. Clinical trials to support FDA 510(k) submission are well underway. "As we gear up for FDA clearance, it's very motivating to see how excited the U.S. ecosystem is about our novel approach to detecting sepsis and its potential impact on lifespan and healthcare costs," said Nelson Dumas, Director of the U.S. Subsidiary of Abionic.

Source: [Abionic](#)

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