

Q-linea achieves CE-mark conformity to IVDR for the ASTar instrument

Q-linea AB (publ) (OMX: QLINEA) today announces that the company has achieved In Vitro Diagnostics Regulation (IVDR) status for the ASTar Instrument.

The regulation IVDR ((EU) 2017/746) is replacing the previous directive (98/79/EC), and IVDR CE-mark is a requirement to continue to place devices on the market after the transition period.

A Notified Body IVDR application is ongoing to achieve IVDR conformity assessment certificate for the ASTar BC G- Kit.

“We are very proud of being able to meet the timeline for CE-mark conformity to IVDR for the ASTar Instrument. The transition from the IVD directive to IVDR is the largest change in the regulation of diagnostic products in Europe for decades, and I am truly amazed about all the hard and excellent work performed by the team to make the transition and stepping up to new demands,” said Jonas Jarvius, CEO of Q-linea.

About ASTar Instrument and ASTar BC G-Kit

ASTar Instrument and ASTar BC G-Kit already deliver the broadest answer regarding the combination of the number of antibiotics and the number of double dilution steps of each antibiotic, in a single analysis for gram-negative bacteria. The test enables the analysis of gram-negative bacteria, including difficult-to-grow so-called fastidious bacteria, which satisfies the need for rapid and comprehensive results to support optimal treatment decisions.

ASTar Instrument and ASTar BC G- Kit are CE-marked but not FDA 510(k)-cleared and not available for sale in the United States.

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About Q-linea

Q-linea is an innovative infection diagnostics company that primarily develops instruments and disposables for rapid and reliable infection diagnostics. Our vision is to help save lives by ensuring antibiotics continue to be an effective treatment for future generations. Q-linea develops and delivers preferred solutions for healthcare providers, enabling them to accurately diagnose and treat infectious disease in the shortest possible time. The company's lead product ASTar® is a fully automated instrument for antibiotic susceptibility testing (AST), giving a susceptibility profile within six hours directly from a positive blood culture. For more information, please visit www.qlinea.com.

Attachments

[Q-linea achieves CE-mark conformity to IVDR for the ASTar instrument](#)