Q-linea receives IVDR certification

Q-linea AB (publ) (OMX: QLINEA) today announces that the company has received certification according to the new and more comprehensive EU regulation for in-vitro diagnostic medical devices, IVD

The certification, issued by the notified body TÜV SÜD, applies to Q-linea's quality management system (QMS) as well as the product groups consumables and analysis software for testing antibiotic resistance.

"I am very happy that we have achieved this high level of quality for our processes and products and that we have achieved IVDR certification at such an early stage. The certification is proof of a comprehensive quality focus in the company and an important basis for the development of new products and updates to existing products on the European market. This clearly gives us a market advantage compared to companies that have not yet achieved IVDR status," says Jonas Jarvius, CEO of Q-linea.

The IVDR certification is a prerequisite for being able to CE-mark ASTar BC G- Kit according to IVDR. The goal is to obtain a CE-mark for ASTar BC G-Kit according to IVDR before the summer. ASTar Instrument is CE-marked according to IVDR since May 2022.

About the IVDR certification
Q-linea's products ASTar Instrument and ASTar BC G- Kit (consumables and analysis software) were first CE-marked according to the directive 98/79/EC for in-vitro diagnostic medical devices in May 2021. The new and more comprehensive regulation for in-vitro diagnostic medical devices, IVDR (EU) 2017/746, entered into force on May 26, 2022, and Q-linea implemented all applicable IVDR requirements and CE-marked ASTar Instrument according to IVDR in May 2022. For products that require a notified body for CE marking according to IVDR, there is an extended transition period, among other things due to the complexity of the new regulation and lack of capacity of notified bodies. However, no significant changes to CE-marked products according to the previous directive may be implemented after May 26, 2022, and no new products may be CE-marked according to the directive during the transition period. For ASTar BC G- Kit, certification by a notified body is required to CE-mark according to IVDR, which is now possible after IVDR certification by TÜV SÜD.

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

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