Press Release
22 October 2024 15:00:00 CEST

Qlucore Passes Key Milestone Towards CE-Mark Registration for Qlucore Diagnostics: Technical Documentation Approved

Qlucore, a leading software development provider for precision cancer diagnostics, has entered the last and final stage of certification of a CE-marked medical device for in-vitro diagnostics. The technical documentation according to IVDR 2017/746 Annex IX Chapter II for Qlucore Diagnostics, is now approved by the notified body, BSI. The final stage involves obtaining certification for the quality management system. Having achieved approval of the technical documentation, the company is now significantly closer to bringing Qlucore Diagnostics to market.

The specific type of cancer being targeted for Qlucore Diagnostics is B-Cell Precursor Acute Lymphoblastic Leukemia (BCP-ALL) in children. This is a condition where mortality and treatment-related complications remain high. However, for a medical device to be utilized in healthcare diagnostics, IVDR regulations require the device to have a CE mark, a certification showing that the device has been assessed to meet high health, safety and environmental standards. This process was initiated by Qlucore AB last year. The performance study as well as the complete technical documentation have now been approved. The final stage of certification, to obtain acceptance of the quality management system, is well underway. The estimated timeframe for regulatory approval of Qlucore Diagnostics BCP-ALL is February 2025.

"The approval of all technical documentation is a major step. We now look forward to receiving this certification which will enable the launch of Qlucore Diagnostics for use in pediatric leukemia diagnostics. We are not aware of any other IVDR-approved software in this area." says Carl-Johan Ivarsson, CEO of Qlucore.

The software is intended for qualitatively analyzing the genetic changes that may lead to BCP-ALL. The analysis is based on gene activity levels and the identification of gene fusions. A machine learning-based classifier generates a probability score to determine the genetic sub-type of a tumor*. The results obtained from the Qlucore Diagnostics BCP-ALL can assist in the initial classification and management of pediatric patients with suspected or diagnosed BCP-ALL.

Qlucore Sweden Ideon Science Park, Scheelevägen 17, 223 70 Lund.
Qlucore USA 900 Third Avenue, 29th Floor, New York, NY 10022.

Qlucore diagnostics will be available to clinical laboratories across Europe.

*This is a simplified description of the planned use of the product. The exact usage will be determined in conjunction with regulatory approval.

Certified Advisor

FNCA Sweden AB
Web: www.fnca.se

Contacts

Press contact:
Michael Bull
Brookscomm
Phone: +44 (0) 1483 537 890
Email: michael@brookscomm.com

Qlucore contact:
Carl-Johan Ivarsson, CEO
Phone: +46 (0) 46 286 31 14
Email: carl-johan.ivarsson@qlucore.com

About Qlucore

Qlucore is a leading provider of new generation intuitive bioinformatics software for research and precision and companion diagnostics. Qlucore's mission is to make it easier to analyze the huge amounts of complex data generated by innovations in the fields of genomics and proteomics by providing powerful visualization-based bioinformatics data analysis tools for research and precision diagnostics. Qlucore Omics Explorer software is a easy to use bioinformatics software for research in the life science, plant- and biotech industries, as well as in academia. Qlucore Diagnostics and Qlucore Insights are software platforms with built in AI-based machine learning for multi-omics companion and precision diagnostics. Qlucore was founded in 2007 in Lund, Sweden and has customers in about 25 countries around the world, with sales offices in Europe and North America, and distribution in several countries in Asia. Qlucore is listed on the Nasdaq First North Growth market. www.qlucore.com

Attachments

Qlucore Passes Key Milestone Towards CE-Mark Registration for Qlucore Diagnostics: Technical Documentation Approved