

Press Release

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Qlucore Diagnostics for Pediatric leukemia takes a Significant step closer to CE marking

-Qlucore Submits Technical Documentation to Notified Body

Qlucore, a leader in software development for precision cancer diagnostics, has taken the final major step in the process towards a CE-marked medical device for in-vitro diagnostics by submitting the technical documentation to a Notified Body. The CE marked product, Qlucore Diagnostics, is due to be launched in February 2025.

The targeted cancer disease is acute lymphoblastic leukemia (ALL) in children, a condition where mortality and treatment-related complications remain high.

In order for a medical device to be used in healthcare diagnostics, IVDR regulations require the device to have CE marking. The performance study initiated by Qlucore in December 2023 is now complete, with expected positive results. The technical documentation can now be reviewed and approved by the Notified Body. Qlucore has contracted BSI (British Standards Institute) as the Notified Body, and the Institute will conduct a formal review of the product's safety and performance. The result is regulatory approval and CE marking, and the estimated timeframe for regulatory approval of Qlucore Diagnostics BCP-ALL is February 2025.

The intended use of the software is to qualitatively analyze the genetic changes that may cause the disease condition BCP-ALL. This is done based on gene activity levels and the identification of gene fusions. The classification into genetic subgroups is performed using a machine learning-based classifier and subsequently, a probability is presented that indicates the likelihood that the patient belongs to one of six defined subgroups. *)

"Completing the performance study and having all technical documentation in place is the final major step. We now look forward to the approval that enables 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 intended customers are clinical laboratories in Europe.

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



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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

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