



Qlife CE-mark for COVID-19 test delayed 2-3 months – application for temporary approval in Denmark due to public health interest submitted

Qlife was expecting CE-mark for its COVID-19 test during October, as communicated in the Q2 2020 report. The approval has been delayed due to regulatory requirements, and the company is now expecting approval within 2 - 3 months. In the mean time, Qlife has submitted an application for temporary approval to put the test on the market in Denmark prior to CE-mark in the interest of protecting health.

Qlife was originally expecting CE-mark for the product in October, but the company is now expecting approval within the coming two to three months. In the mean time, Qlife has submitted an application to the Danish Medicines Agency (Lægemiddelstyrelsen) for placing the company's COVID-19 test on the market prior to CE-marking in a direct response to the pandemic "in the interest of the protection of health"

"Qlife like any other IVD company now has to follow the increased regulatory requirements to obtain sufficient data to support clinical evidence, however in order to address the immediate and critical need to create virus-free locations for especially elderly and vulnerable people, we have decided to apply for market approval in Denmark prior to CE-marking", says Thomas Warthoe, CEO Qlife.

This disclosure contains information that Qlife Holding AB is obliged to make public pursuant to the EU Market Abuse Regulation (EU nr 596/2014). The information was submitted for publication, through the agency of the contact person, on 30-10-2020 12:00 CET.

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About Qlife

Qlife is a medical device company that seeks to revolutionize the clinical biomarker market for whole blood testing by taking it out of the lab and into the homes. This will facilitate easy access to blood sample results and in turn facilitate increased monitoring of parameters that enables care improvement.

Shares for Qlife are being traded on Nasdaq First North Growth Market in Stockholm with G&W Fondkommission as certified advisor (phone: +46 (0) 8-503 000 50, e-mail: ca@gwkapital.se).

Read more on [Egoo.health](https://egoo.health), [Qlifeholding.com](https://qlifeholding.com) or follow us on [LinkedIn](https://www.linkedin.com/company/qlife).