

Qlife: application for temporary approval in Denmark "in the interest of health protection" receives preliminary rejection by the Danish Medicines Agency

Qlife announces that its application for placing the company's COVID-19 test on the market prior to CE-marking this afternoon has received a preliminary rejection by the Danish Medicines Agency (Lægemiddelstyrelsen).

In parallel to the ongoing process of preparing and putting together the dossier for the CE-mark, Qlife has submitted an application for placing the product on the market at this stage, as it offers a unique opportunity in the fight towards COVID-19. Qlifes announces that the application to launch the company's COVID-19 test on the market for professional use prior to CE approval has received a preliminary rejection from by the Danish Medicines Agency. The Danish Medicines Agency see no reason to grant an exemption for medical equipment that does not currently have a CE-mark and that there are other diagnostic alternatives on the market. Qlife now has 14 days to respond to the preliminary announcement.

"We are of course surprised that The Medicines Agency makes a different assessment than us about the immediate need for safe and reliable tests. However, as previously communicated, we are working towards a CE approval, and today's announcement has no major impact on our long-term plan. We will now evaluate today's decision and how to proceed with the current application along with our parallel process towards a CE approval for our COVID-19 test," says Thomas Warthoe, CEO of 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 13-11-2020 17:55 CET.

For more information please contact:

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About Qlife

Q life 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, Qlifeholding.com or follow us on LinkedIn.