Calmark's first product, Neo-Bilirubin, obtains CE Mark

Calmark Sweden AB (publ) announces today that the product Calmark Neo-Bilirubin has obtained its CE marking in accordance with the IVD directive. The product can now be sold to and used in healthcare within the European Union.

The IVD directive encompasses requirements regarding safety, performance and function. The quality assurance of Calmark's first product, Neo-Bilirubin, is now successfully completed in all these regards.

In addition to giving Calmark authorization to sell the product within the EU, the CE Mark further opens up opportunities for accelerated registration on other markets, such as the prioritized countries in South-East Asia. Calmark intends to build on the CE mark by establishing agreements with distributors in other parts of the world where the marking makes it possible to fast-track market approval.

”*It is with heartfelt satisfaction that we announce the CE conformity marking of our first product*,” says Anna Söderlund, CEO. "*The CE Mark is the endpoint of the development project and the start of the launch process; I would like to extend my gratitude to my fabulous team for their competence and the massive effort they have invested in this product.*"

Calmark Neo is a platform that consists of a reader, a related software and a set of single-use tests, with each test intended for a specific biomarker. Since the reader obtains its CE marking together with each respective biomarker, the initial project to develop the Neo-Bilirubin product, has been the most extensive. The platform can be used both in hospitals and in point-of-care settings such as paediatric health centres, mobile units, etc. Calmark has a distributor agreement with Triolab AB regarding marketing and sales on the Swedish market. Dialogue with distributors on other priority markets is underway.

This information is information that Calmark Sweden AB is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act. The information was submitted for publication, through the agency of the contact person set out above, on 21 April 2020, 16:30 CEST.

Every care has been taken in the translation of this document. In the event of discrepancies, the Swedish original will supersede the English translation.

For more information about Calmark Sweden AB, please contact:

Anna Söderlund, CEO
Telefon: +46 70 213 25 35
E-post: anna.soderlund@calmark.se
www.calmark.se

Calmark Sweden AB is a medical technology company developing a point-of-care (POC) analysis method with easier and faster sampling of medical conditions in newborns. The unique test platform consists of a reader and single-use products. The first three tests are being launched in 2020. WHO expects 1.5 billion children to be born worldwide prior to 2030. In the Western world, the introduction of POC diagnostics is resulting in huge savings and shorter care chains. In less developed healthcare systems, the product will offer decision-making support, which is currently lacking, since the access to hospital laboratories often is limited. Calmark aims to become the global leader in POC diagnostics for newborns and, in the long term, to offer all relevant tests for the first period of life. The B share is listed on the Spotlight Stock Market and is traded under the CALMA B ticker. Read more at www.calmark.se/eng/home.