Calmark compliant with IVDR from today

Anna Söderlund, CEO of Calmark Sweden AB (publ) has today signed the 'Declaration of Conformity' showing that Calmark has adapted the quality system and the technical documentation to comply with the new IVDR regulations. The documentation will now be sent to the Swedish Medical Products Agency. Compliance with the IVDR is a requirement to maintain the CE marking of existing products from May 26, 2022 onwards.

"It has been extensive work to adapt our operations and our entire quality system to comply with the new regulations," says Anna Söderlund, CEO of Calmark. "I am very proud that we completed this in advance of the deadline. Each individual document has been reviewed and I would especially like to thank our QA team, Michael Lundh and Annika Kaisdotter-Andersson for their fantastic efforts!"

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

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Calmark Sweden AB is a medical technology company that develops and markets a point-of-care (POC) analysis method with easier and faster diagnostics of medical conditions in newborns. The unique test platform consists of a portable instrument and test cassettes for various biomarkers. The first test, Neo-Bilirubin, was launched to the market in 2020. 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 a decision 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. In addition to products for newborns, Calmark sells a POC test for assessment of COVID-19 disease severity. 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.