PolarCool completes stage 1 of the MDR process and begins the final phase

PolarCool AB (publ), has successfully completed the first stage of the audit process for its own quality system ISO 13485 under the new MDR regulations.

PolarCool develops and markets the PolarCap® System, a product that alleviates the effects of concussion injuries. PolarCap® is primarily used by sports organizations and facilities in contact sports such as ice hockey, rugby, football, and handball, as well as in sports with an increased risk of concussion.

The audit, carried out with Intertek, a Notified Body (NB), involved an on-site evaluation of the company's quality system documentation and has been approved, paving the way for the final audit, stage 2, scheduled for mid-June 2023, as the last step for the company to obtain its own MDR certificate.

Currently, PolarCap® System is certified under BrainCool AB's QMS for quality assurance, but the product will be transferred to PolarCool's own QMS once the company receives its own approval, resulting in significant cost savings.

PolarCool CEO Erik Andersson comments:

> *- The fact that we have now passed the first step in the certification process means that we have taken a big step closer to our long-term goal - to have our own QMS system. We are now looking forward to the planned final audit of Intertek in June, to then have everything in place to obtain approval for the company's own quality system.*

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About PolarCool AB (publ)
PolarCool AB (publ) is a medical device company that develops, markets, and sells products for sports medicine. The company focuses on treatment of concussive and sub-concussive brain injury with the portable cooling device PolarCap® System. PolarCool AB (publ) is based in Lund, Sweden, and its shares are listed on Spotlight Stock Market.