

PolarCool make progress in the MDR process - final audit completed

PolarCool AB (publ), has successfully completed the final, stage 2, audit together with Intertek. The timeline for the company stands with expected MDR approval in autumn 2023.

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 company has completed the ongoing process with Intertek, a Notified Body (NB) taking another important step towards obtaining approval for PolarCool's own quality system ISO 13485 within the new MDR regulations. In May it was announced that PolarCool had successfully completed the first step in the certification process and been approved to carry out the second and final audit which has now been completed. The timetable for the final approval remains and is expected in the fall of 2023.

Today, 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 the approval, resulting in significant cost savings.

PolarCool CEO Erik Andersson comments:

- Completing the final audit means that we are one step closer to obtaining our own QMS system. The audit response from Intertek has been positive and we are now looking forward to completing the final tasks needed to obtain an MDR certificate.

For more information

Erik Andersson – CEO

+46 – 73 860 57 00

E-mail: erik.andersson@polarcool.se

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.