

PolarCool receives timeline for MDR certification

The med-tec company PolarCool AB (publ) announces that it has received a timeline from Intertek for approval of the company's own quality management system (QMS), under the EU's new Medical Device Regulation (MDR).

In an ongoing process with the Notified Body (NB) Intertek, PolarCool has made important progress in obtaining approval for the company's own quality management system ISO 13485 within the new MDR regulations. Intertek has provided PolarCool with a timeline for the upcoming certification process, the first part of which will begin in this autumn. The final part, which is a stage 2 audit, is planned to take place during June 2023. This is the last step for PolarCool in obtaining its own MDR certificate.

Today, PolarCool's med-tech product PolarCap® System is certified through the current cooperation agreement with BrainCool AB, which means that the product is manufactured and sold under BrainCool's QMS for quality assurance. When PolarCool receives its own approval, the product will be transferred to the company's own QMS.

PolarCool CEO Erik Andersson comments:

- The fact that we have now received a slot, and a timeline from Intertek means that we have taken a big step closer to our long goal of having our own QMS. The new MDR regulations from the EU place a very heavy burden on the Notified Bodies that issue certificates, which has resulted in a long queue time to start the process.

- At the same time, the current cooperation agreement with BrainCool has given us the opportunity to use their QMS, allowing us to be able to market and sell our product in Europe.

PolarCool develops and markets the product PolarCap® which alleviates the effects of concussion. The primary users of PolarCap® include sports clubs, organizations, and facilities in contact sports such as ice hockey, rugby, and handball, but also other sports with an increased risk of concussion.

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.