

Finalization agreement signed between PolarCool AB (publ) and BrainCool AB (publ) - annual cost of SEK 2 million ended

The med-tech companies PolarCool AB (publ.) and BrainCool AB (publ.) collectively announce that they have signed a finalization agreement. The agreement confirms that PolarCool's medical technology product PolarCap® will now be manufactured and sold under PolarCool's own quality management system (QMS) and that previous collaboration agreements have been terminated as planned.

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

The finalization agreement replaces the previous cooperation agreement with BrainCool which was terminated on November 1st 2023. This entailed an annual cost of SEK 2 million for PolarCool. However, since PolarCool received the ISO 13485:2016 certificate for its Quality Management System (QMS) and an MDR 2017/745 certificate for the PolarCap® System as a product, it enables the company to be the legal manufacturer for new products put on the market (see PolarCool's press releases on 11th and 25th of October 2023). During this year PolarCool has built up its own Quality Assurance organization for this.

Furthermore, the finalization agreement regulated the respective parties' responsibilities for products that are already on the market. BrainCool will continue to be the legal manufacturer for these, whereas PolarCool will have a responsibility towards BrainCool for all regular Quality Assurance around the products, something that already is carried out by PolarCool.

PolarCool CEO Erik Andersson comments;

- The fact that we can now stand on our own two feet and act as a legal manufacturer is a very important milestone and also means a significant cost saving for PolarCool. We are grateful for the collaboration with BrainCool, which has given us the opportunity to begin the market introduction for PolarCap® in Europe. We now look forward to focusing on the continuous establishment of PolarCap® in the European market.

BrainCool CEO Martin Waleij comments;

*- It is a significant quality stamp that the product PolarCap® System received the MDR certificate. Here, PolarCool as a company is really at the forefront. That fact that early cooling works continues to be confirmed, something that was demonstrated both in the published study within Swedish ice hockey with PolarCap®, but also in BrainCool's studies in stroke and cardiac arrest.
- Even though the parties' cooperation to make PolarCool independent has ended, I am convinced that the companies' joint history will be able to mean continued cooperation.*

For more information

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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.