

PolarCool extends agreement with BrainCool regarding quality assurance

PolarCool AB (publ) and BrainCool AB (publ) have extended a cooperation agreement in relation to the quality assurance of the company's medical technology product, PolarCap® System, which will continue to be manufactured and sold under BrainCool's quality system (QMS). The renewed agreement runs until December 31, 2023.

PolarCool develops and markets the product PolarCap System, 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, football and handball, but also other sports with an increased risk of concussion.

The extended agreement between the companies means in practice that BrainCool acts as a legal manufacturer of the product in the EU market according to the quality system (QMS) ISO 13485.

In September, PolarCool received a timetable from Intertek for the company's own certification of the quality system within the new MDR regulations. The final stage 2 audit, is planned to take place in June 2023. This is the last step for PolarCool to obtain its own MDR certificate. Once PolarCool has received the approval, the rights to the product will be transferred to the company, and then manufactured and sold under PolarCool's own quality system.

PolarCool CEO Erik Andersson comments;

-The fact that we have now extended our cooperation agreement with BrainCool regarding quality assurance and recently strengthened our financial position, enables us to now focus on continuing to establish the PolarCap in the European market as a standard treatment for sports-related concussions.

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.