

PolarCool receives ISO 13485:2016 certificate

The med-tec company PolarCool AB (publ) have received an ISO 13485:2016 certificate issued by Intertek Medical for the Company's Quality Management System (QMS).

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.

In the ongoing MDR process with Intertek Medical, a Notified Body (NB), the company has addressed all identified deviations from previous audits. This work has now resulted in certification of the Company's Quality Management System (QMS) for medical technology products, which means that it meets the requirements of EN ISO 13485:2016. The company is now only awaiting certificate also for the company's product PolarCap® System.

Until now, the PolarCap® System has been certified through the current agreement with BrainCool AB (publ), which means that the product is manufactured and sold under BrainCool's QMS for quality assurance. With this certification in hand, PolarCool will no longer be reliant on BrainCool's QMS, marking a significant step towards self-sufficiency and enhanced operational efficiency. This development will enable the company to begin the transfer of the PolarCap® System into the company's own QMS, promising substantial cost savings moving forward.

PolarCool CEO Erik Andersson comments:

- The fact that we have now received a certificate for our own Quality Management System, and thus achieved one of the year's most important milestones, is very satisfying. That we as a small company have succeeded in this is something I am incredibly proud of. Our Quality Assurance team has done a tremendous amount of work over several years.

This information is information that PolarCool (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out herein, on October 11th, 2023.

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.