

## **PolarCool Completes MDSAP Process Enabling Application for Product Approval in Canada**

**The med-tech company PolarCool AB (publ.) has received its MDSAP approval (Medical Device Single Audit Program) following the successful completion of Stage 1 and Stage 2 audits conducted by Intertek. The MDSAP process is therefore finalized, and PolarCool can now proceed with the application for market approval of PolarCap® in Canada.**

The MDSAP approval means that PolarCool as a company is approved to launch products in several markets outside Europe, such as Canada, the United States, and Australia, among others. The approval replaces separate approvals of the company's quality management system by each market's respective regulatory authority. With the MDSAP approval in place, only a product approval is now required for each individual market. PolarCool will initially focus on North America, with the objective to obtain product approval for PolarCap® from Health Canada and the FDA during the first half of 2026.

The completed MDSAP process has included a comprehensive review of the company's quality management system by Intertek, which is also PolarCool's Notified Body (NB). After PolarCool communicated in August and November that the company had successfully completed the two audits, the final review of the results and all non-conformities has now been completed with an approved outcome.

PolarCool's CEO Erik Andersson comments:

- *Receiving our MDSAP approval is an important milestone for PolarCool's expansion outside of Europe. It confirms the quality of our quality management system, and with this in place we can fully focus on the next step - applying for and obtaining product approval for PolarCap® in Canada and the United States as quickly as possible.*

*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 March 6<sup>th</sup>, 2026.*

### **For more information**

Erik Andersson – CEO PolarCool AB (publ.)

+46 – 73 860 57 00

E-mail: [erik.andersson@polarcool.se](mailto:erik.andersson@polarcool.se)

### **About PolarCool AB (publ.)**

*PolarCool AB (publ.) is a Swedish medical technology company focused on developing and marketing products in the sports medicine field. Its primary product, **PolarCap®**, is designed to reduce the impact of concussion through targeted brain cooling. PolarCool works with professional teams across Europe in rugby, football, and ice hockey and its shares are listed on Spotlight Stock Market.*