

## **Progress for PolarCool in the MDSAP Process – Further Steps Toward Launch in Canada**

**The med-tech company PolarCool AB (publ.) has successfully completed the final stage 2 audit in its MDSAP process (Medical Device Single Audit Program). Final approval is expected at the beginning of 2026, after which the company can proceed with its application for product approval for PolarCap® in Canada.**

With the [MDSAP](#) certification, PolarCool will be qualified to market and sell its products in additional markets outside of Europe. This certification means that only product-specific approval is required for each new region. PolarCool will first prioritize Canada, with the goal of securing Health Canada product approval for PolarCap® in Q2 2026

In the ongoing MDSAP process with Intertek, a designated Notified Body (NB), PolarCool has taken another significant step forward toward MDSAP certification. In August, the company announced that it had successfully completed the first stage of the certification process and received approval to the second and final audit - which has now been completed.

PolarCool's CEO, Erik Andersson, comments:

- *Completing the final audit means that we are one step closer to obtaining our own MDSAP certificate. The audit response from Intertek has been positive, and we now look forward to completing the final actions required to receive the certificate and then, as soon as possible, submit an application to Health Canada for product approval in the Canadian market for PolarCap®.*

### **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®**. PolarCool AB (publ.) is based in Lund, Sweden, and its shares are listed on Spotlight Stock Market.*