



BrainCool AB (publ): Annual audit conducted by TÜV SÜD

The German notified body, TÜV SÜD has conducted an annual audit of the company's quality systems and products. Due to Covid-19, this year's audit was carried out in the form of a so-called "remote audit " without a physical meeting.

The outcome of the audit was very good and only three nonconformities were issued, which are to be answered within 30 days, and corrective actions are already ongoing to close out the deficiencies.

Our notified body conducts annual audits and ensures that our CE-marked medical devices meet approved safety and performance requirements, as well as component-level specifications to finished products at all times. This audit was the second surveillance audit, which means that next year's audit is a recertification audit. Unannounced audits are also performed, usually once every three years, the latest being held in January this year, as previously announced.

BrainCool AB recently received an updated EC certificate (MDD 93/42/EEC Annex II) for both non-invasive and invasive hypothermia systems valid until 2024-05-26.

For more information

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About BrainCool AB (publ)

BrainCool AB (publ) is an innovative medical device company that develops, markets, and sells leading medical cooling systems for indications and areas with significant medical benefits within the healthcare sector. The company focuses on two business segments, Brain Cooling and Pain Management. BrainCool AB (publ) is based in Lund, Sweden, and its share is listed on Spotlight Stock Market.