PAXMAN
PIONEERS IN SCALP COOLING

The Paxman Scalp Cooling System receives EU MDR certification

Paxman has received EU Medical Device Regulation (MDR) certification from its Notified Body, the British Standards Institution (BSI)

Paxman is amongst the latest companies to achieve MDR approval, reaffirming its commitment to the market, its customers and, most importantly, the patients who will continue to benefit from the use of the Paxman Scalp Cooling System.

The Medical Device Directive 93/45/EEC was introduced in 1993 and there were no changes to the legislation until the significant shift to Medical Device Regulations 2017/745 in 2021, with aim being to modernize and create a robust and long-term legislative framework, with strict inspection by Notified Bodies to ensure the highest levels of safety.

The introduction of the MDR 2017/745 means more stringent requirements, particularly in clinical and post-market review data. As a result, Paxman, along with many medical device companies within the EU, have had to make significant time and financial investments to improve processes to capture and analyse the data required to continue trading in the European Union. Since submission of Paxman's initial application for MDR in 2019, the Technical & Quality Department have effected extensive changes to the technical files within the Quality Management System (QMS) to comply with the new regulations including a full QMS audit, Clinical Evaluation review and extensive Technical Documentation review.

Alexandra Sheldrake, Head of Quality and Operations at Paxman said, "I am extremely proud that Paxman have achieved MDR certification, and particularly of the Quality and Technical teams' dedication, hard work, due diligence and commitment to the quality of our processes and product. Collectively as a team we have overcome considerable challenges to ensure continued availability of Paxman's scalp cooling device. As an SME this is particularly important as we know so many have failed to adapt to the significant changes of the MDR, with some even withdrawing their products altogether. It is humbling that we have achieved MDR certification, something which is acknowledged has been achieved by very few MedTech companies to date."

The EU MDR for medical devices ensures continuity of patient access and care, not only in the EU but in over 100 countries around the world, however only 36 Notified Bodies have been granted audit rights to issue 23,000 certificates for the more stringent and robust certification. It is noted that amongst Small and Medium Enterprises (SMEs) at least 15% and up to 30% still have no access to an MDR-designated Notified Body and for SMEs progress to MDR certification is slower than average.[1]

[1] https://www.medtechdive.com/news/eu-mdr-delay-device-shortage/638491/#:~:text=Noting%20factors%20that%20have%20%E2%80%9Cput,medium%20and%20low%2Drisk%20devices.

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About Us

The Paxman Scalp Cooling System has been developed by the Paxman family to reduce hair loss in breast cancer patients undergoing chemotherapy. The concept behind the system came when the mother of four, Sue Paxman, experienced first-hand the trauma of chemotherapy-induced hair loss. With close to 4,400 systems delivered in to hospitals, clinics and treatment centres around the world, PAXMAN is the leading supplier of Scalp Cooling technology. PAXMAN's scalp-cooling cap is made from lightweight, biocompatible silicone that is soft and flexible, providing a snug yet comfortable fit during treatment. PAXMAN AB (publ) has its headquarters in Karlshamn (Sweden), with subsidiaries in Huddersfield (UK) and Houston, Texas (US).

The PAXMAN share is listed on Nasdaq First North Growth Market.
FNCA Sweden AB is the company's Certified Adviser.

Attachments

The Paxman Scalp Cooling System receives EU MDR certification