

DIGNITANA

DigniCap Delta receives market approval in Japan

Dignitana announces that DigniCap Delta received market approval in Japan from the Ministry of Health, Labor and Welfare (MHLW). In Japan, Dignitana will provide DigniCap Delta to Konica Minolta as a medical device manufacturer, and [Konica Minolta](#) will proceed as a market authorization holder (MAH) to expand into the Japanese market.

Regulatory approval for medical devices in Japan is similar to the FDA clearance process for medical devices in the United States, it is a pathway in which quality, efficacy, and safety are examined and approved according to the classifications established by law.

Based on Dignitana's distribution agreement with Konica Minolta, an initial order was placed in February and a second order for several devices will be placed in early spring 2024 to prepare for launch.

"Introducing DigniCap Delta to the Japanese market is an important milestone for Dignitana as we continue to advance our strategic objectives. Konica Minolta has a long history of innovation as a technology leader in Asia and around the globe and we are honored to have Konica Minolta as a partner to introduce DigniCap Delta's next generation scalp cooling technology to patients in Japan. Their strong market presence and team of experienced professionals bring tremendous value to our company and to oncology providers in Japan," said Catarina Löwenadler, Dignitana CEO.

"Interest in scalp cooling in Japan is very strong, and we are excited to now be able to move forward with sales to customers who have been waiting for this advanced technology," said Toshikazu Imai, General Manager Business development division, Konica Minolta.

Over one million new incidences of cancer are diagnosed annually in Japan. Breast cancer is the most common type of cancer for women in Japan, with over 94 thousand women diagnosed with breast cancer in 2022 (ganjoho.jp).

In order to demonstrate the effectiveness of DigniCap Delta, Konica Minolta initiated a clinical trial targeting breast cancer patients in May 2023 at St. Marianna University Breast & Imaging Center.

With a primary market in the US, the FDA-cleared DigniCap Delta device uses industry-leading thermoelectric cooling to minimize hair loss that is a side effect of chemotherapy prescribed to treat solid tumors such as those from breast cancer, ovarian cancer and prostate cancer. Recognized internationally as a standard of care and quality of life advancement for cancer patients, scalp cooling is a treatment recommendation in the clinical practice guidelines published by [National Comprehensive Cancer Network® \(NCCN\)](#), [European Society for Medical Oncology \(ESMO\)](#), and [Cancer Australia](#). It is available in cancer centers around the globe.

For More Information Contact

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About Dignitana

Dignitana AB is the world leader in clinically superior scalp cooling technology. The company produces The DigniCap® Scalp Cooling System, a patented medical cooling device that offers cancer patients the ability to minimize hair loss during chemotherapy. FDA cleared since 2015, DigniCap provides continuous cooling with high efficacy, safety and patient comfort. Hailed internationally as a life-changing medical advancement for cancer patients, The DigniCap Scalp Cooling System was invented in 1999 by a Swedish Oncology nurse and has been available in Europe since 2001. Dignitana AB is listed on Nasdaq First North Growth Market in Sweden with headquarters in Lund, Sweden and US operations based in Dallas, Texas in the United States. Company subsidiaries are Dignitana, Inc. in the United States and Dignitana S.r.l. in Italy. Certified Adviser is Redeye AB. Learn more at www.dignitana.com or www.dignicap.com.