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Niramaiâ??s breast cancer screening test receives CE mark approval

06 April 2021 | News

NIRAMAIâ??s Thermalytix solution can now be applied to all countries of Europe, as well as applicable to many Asian, African and Middle-East countries.



Niramai, the deep-tech healthcare company at Bengaluru offering an innovative AI-based, radiation-free breast cancer screening test has now received the prestigious CE mark approval, ISO 13485 and MDSAP (Medical Device Single Audit Programme) International Certifications.

The CE mark approval indicates that the product may be sold freely in any part of the European Economic Area. The ISO 13485 and MDSAP certifications endorse medical device manufacturers for their compliance with the international medical device quality standards and regulatory requirements.

NIRAMAI's Thermalytix™ solution and quality management processes were audited by an international notified body consisting of expert auditors from India, Germany and Australia. This CE mark approval shows that the product meets EU requirements for medical devices under MDD93/42/EEC for safety, and performance.

With these quality certifications, NIRAMAI's Thermalytix solution can now be applied to all countries of Europe, as well as applicable to many Asian, African and Middle-East countries.

NIRAMAI test is already being used in renowned hospitals and clinics across various Indian cities, including HCG Hospital, Apollo Clinics, HealthSpring Diagnostics, among others.

Dr Geetha Manjunath, Founder and CEO, NIRAMAI comments, "These certifications enable us to expand our operations internationally and meet the strong global demand we are seeing for our novel solution. Moving forward, we plan to collaborate with renowned radiologists of the National Health Service (NHS) and other key opinion leaders for an initial market testing in Europe, Africa and Asia. In addition, we are in the process of partnering with more Indian healthcare providers for pan India adoption."

Manish Singhal, Founding Partner of pi Ventures and lead investor, NIRAMAI said, With the ISO and CE certification, now Thermalytix can be made available to women beyond India especially in entire Europe, Middle-East and several countries in South-east Asia leading to global impact.

Munehiko Eto, NIRAMAI board member and investor from the Japanese VC Firm, Dream Incubator, said "There is a strong global need for Niramai's breakthrough technology innovation of AI-based screening solution for breast cancer, especially for women with dense breasts."