

CureMetrix Receives ISO 13485:2016 Certification for Artificial Intelligence (AI) Based Mammography Software

Receiving the Quality Management System certification helps the healthcare technology company to bring its AI-based digital mammography solutions worldwide.

SAN DIEGO, CA, UNITED STATES, August 2, 2022 /EINPresswire.com/ --

[CureMetrix®](#), a global healthcare technology company that develops AI-based software for radiology, announced today that it has received the ISO 13485:2016 certification for Quality Management Systems (QMS). This certification helps the company to bring its advanced AI-based digital mammography solutions to more doctors and patients worldwide.



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*Kevin Harris, President of
CureMetrix*

“The ISO 13485:2016 certification process aligns with our strategic focus to bring quality solutions to the market empowering women’s health,” said Kevin Harris, President of CureMetrix. “We are extremely proud of this milestone achieved by our passionate team that reinforces the company’s excellence in the field of Software as a Medical Device (SaMD) to help improve outcomes for patients and providers.”

ISO 13485:2016 is a globally recognized standard of quality and safety for the medical device industry. It provides a

strategic framework to adhere to medical device directives and regulations to ensure an effective, robust, and continuously improving QMS.

The scope of the ISO 13485:2016 certification awarded to CureMetrix covers the design and development of software for digital mammography systems. CureMetrix AI-based solutions for

mammography include:

cmTriage® is the first FDA-cleared software intended to provide a notification triage code to the radiologist's mammography worklist based on the presence of a suspicious region of interest found by the underlying algorithm. This workflow optimization tool enables a radiologist to customize their mammography worklist based on cases that may need immediate attention.

cmAssist® is an investigational computer-aided detection (CAD) software that leverages AI to help radiologists identify, mark, and score regions of interest on screening mammograms.

cmDensity™ is an AI-based software that helps radiologists classify and report breast density accurately and consistently reducing inter and intra-reader variability.

cmAngio® is an investigational AI-based software that helps doctors assess a patient's age-adjusted risk of heart disease. cmAngio produces a CureMetrix Bradley Score™ based on the existence and characteristics of breast arterial calcifications in the mammogram. This proprietary score can then be used to help the care team assess the patient's age-adjusted percentile of breast arterial calcifications in their mammogram which have been shown to be associated with coronary heart disease. The Bradley Score can be tracked over time to help patients and doctors understand their changing health profile.

"Our team is dedicated to helping physicians streamline their workflow, improve patient outcomes, reduce healthcare costs, and better screen for and detect disease early," continued Harris. "Using the power of AI for medical imaging to read mammograms enables radiologists to do their best work and impact more patients' lives."

To learn more about [CureMetrix Solutions](https://www.curemetrix.com), please visit [curemetrix.com](https://www.curemetrix.com).

About CureMetrix

CureMetrix is a global leader in Artificial Intelligence for medical imaging, committed to advancing technology that improves disease detection and cancer survival rates across the globe. Its mission is to help save lives with early and more accurate disease detection and support improved clinical and financial outcomes, delivering technology that radiologists, healthcare systems, and patients can rely on with confidence. Visit www.CureMetrix.com

Disclaimer: cmTriage® is FDA-cleared for commercial use in the U.S. cmTriage® and cmAssist® are ANVISA cleared in Brazil. cmAngio® and cmDensity™ are in development and not available for commercial use in any country.

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