

# CureMetrix Receives Medical Device Single Audit Program (MDSAP) Certification

*CureMetrix Achieves MDSAP Certification, Reinforcing Commitment to safety, compliance and accelerating the global expansion of AI-based women's health solutions*

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[CureMetrix](#)<sup>®</sup>, a leader in AI-based solutions for mammography, announces that it has achieved certification under the [Medical Device Single Audit Program \(MDSAP\)](#). This additional certification affirms that the company's medical device manufacturing processes meet the regulatory and compliance requirements of Australia, Brazil, Canada, and the United States.



As outlined by the US Food & Drug Administration (FDA), the Medical Device Single Audit Program (MDSAP) allows a single regulatory audit of a medical device manufacturer's quality management system (QMS) to satisfy the requirements of multiple regulatory agencies. The scope of the MDSAP certification awarded to CureMetrix covers the design, manufacture, servicing, installation, and distribution of software for digital mammography systems. The MDSAP streamlines the auditing process, providing manufacturers with a comprehensive approach to meet international regulatory standards efficiently.

"With this milestone, we are poised to introduce our innovative solutions to new markets, ensuring they continue to meet the highest global regulatory and quality standards." said Rekha Anand, Senior Director of Regulatory Affairs. "This certification paves the way for CureMetrix to apply for the regulatory approval of cmAngio<sup>®</sup> in Canada and Australia expanding our reach beyond the US and Brazil". Since first achieving [ISO 13485 certification](#) in 2022, CureMetrix has continued to pursue excellence in quality. This achievement is indicative of CureMetrix's commitment to meeting and exceeding global regulatory standards and ensuring the delivery of high-quality, safe, and effective solutions across its markets.

The MDSAP certification underscores CureMetrix's unwavering commitment to maintaining the

highest standards in quality management systems worldwide, further solidifying the company's position as a trusted leader in the medical device industry.

"Achieving MDSAP certification along with our ISO13485 certification required substantial preparation, an enterprise-wide commitment to quality, and aligns with our strategy to bring cmAngio to the global market. As the only tool cleared to detect and localize Breast Arterial Calcifications, we remain steadfastly committed to improving women's health around the world," said Kevin Harris, President of CureMetrix.

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Brock Anderson

CureMetrix

+1 858-333-5830

info@curemetrix.com

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