

DeepTek's Chest X-Ray AI solution receives CE MDR Class IIb certification

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Pune-based startup DeepTek, a leading provider of artificial intelligence (AI)-powered radiology solutions, has announced that its Chest X-ray AI solution has received CE certification under the European Union Medical Device Regulation (EU MDR) as a Class IIb medical device.

The Chest X-ray AI solution is designed to assist physicians in interpreting frontal chest X-rays (chest anterior and posterior). Powered by advanced machine learning, the solution detects a host of lung conditions such as nodules, lung masses, tuberculosis, pneumothorax, and over 20 other findings, including rib and clavicular fractures.

In addition, the solution identifies multiple medical devices commonly encountered in inpatient and ICU settings, such as chest leads, pacemakers, and various tubes, providing critical support in complex clinical scenarios.

A unique feature of this solution is its ability to interpret pediatric chest X-rays, including the detection of pediatric tuberculosis and pneumonia, enhancing diagnostic capabilities in younger populations, a segment often underserved by conventional AI models.

The certification enables DeepTek to expand the availability of its solution across Europe and other CE-mark recognised regions, offering a powerful tool to enhance productivity, reduce diagnostic delays, and support quality care delivery at scale.

The need for such solutions is particularly urgent in regions grappling with a high tuberculosis (TB) burden and limited access to expert radiology. With a staggering TB burden and growing radiology workload, CE certification paves the way for deployment across Europe, Asia, Africa, and other CE-mark-recognised regions where AI-driven diagnostics are not just valuable, but vital.