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Qure.ai’s AI-Powered TB solution gets US FDA clearance

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Latest regulatory accolade for Qure.ai joins 4 FDA clearances & 61 EU MDR CE mark approvals over the last 18 months

Mumbai-based startup Qure.ai has received breakthrough device designation from the US Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) for its artificial intelligence (AI)-powered Tuberculosis (TB) solution, qSpot-TB.

This latest regulatory accolade for Qure.ai joins four FDA clearances and 61 European Union Medical Device Regulation (EU MDR) CE mark approvals over the last eighteen months.

The qSpot-TB is a second-read computer aided detection and diagnosis device that analyses chest X-rays to localise all noted radiological signs suggestive of TB and provide an accompanying conclusion regarding the presence or absence of TB. This may support clinical workforces, especially during a recent uptick of TB incidences in developed nations including the United States (US).

The breakthrough device designation granted to Qure’s qSpot-TB device by the US FDA marks a step-forward in the field of tuberculosis AI-assisted diagnosis. TB is a highly infectious disease affecting the lungs and is not just the premise of developing nations. Rates of TB in western societies such as the UK and USA have ticked upwards following the COVID-pandemic, magnifying the need for continued focus on detection and screening.