

TECHNICAL REPORT

EU AI ACT CONFORMITY // ANNEX IV (EU) 2024/1689 (AI Act)

SYSTEM IDENTITY

MedScan-AI Diagnostic Suite (v4.1.0-stable)

INTENDED PURPOSE

Automated detection of pulmonary abnormalities in adult thoracic X-ray images.

HARDWARE

Nvidia A100 Tensor Core GPU Cluster /
Local Edge Gateway v2

OVERSIGHT

Radiologist-in-the-loop (Level 4 -
Mandatory Verification)

DATA GOV.

Curated DICOM dataset from NIH
OpenSource and Private Hospital Partners
(2022-2025).

I. RISK MANAGEMENT (ARTICLE 9)

Is there a documented risk management system for the entire lifecycle?

COMPLIANT

JUSTIFICATION / EVIDENCE

Risk Management Framework (RMF) v4.2 is implemented, tracking risks from design through clinical trial and production.

Are testing methodologies defined to ensure consistent performance?

GAP

REMEDATION PLAN

To be implemented within 30 days. Implement automated benchmarking against the "Golden Dataset" (Annex IV, 3b).

Are residual risks mitigated to the best extent possible?

COMPLIANT

JUSTIFICATION / EVIDENCE

Residual risks concerning 'False Negatives' are mitigated via a mandatory secondary human review requirement in the UI.

Is there a process for post-market risk monitoring?

COMPLIANT

JUSTIFICATION / EVIDENCE

The Post-Market Surveillance (PMS) plan triggers monthly data drift analysis reports.

II. DATA AND DATA GOVERNANCE (ARTICLE 10)

Are training and testing datasets relevant and representative?

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EUART PREVIEW

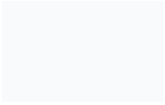
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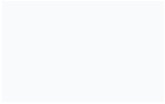
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EUART PREVIEW

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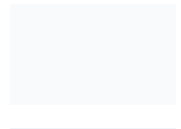


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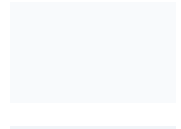


Are there measures to ensure overseers do not face adverse consequences for overriding AI?

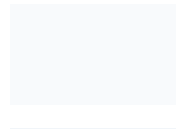
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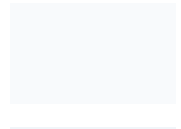
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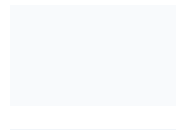
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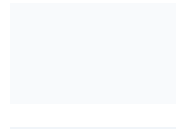
EUART PREVIEW



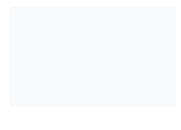
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REFERENCED ATTACHMENTS (ANNEX IV.1.G)

Technical_Annex_IV.pdf

Clinical_Evaluation_v9.docx

Note: The documents listed above are physically or digitally annexed to this conformity report and form an integral part of the technical documentation.

This Technical Documentation Dossier is structured in accordance with Annex IV of Regulation (EU) 2024/1689 (AI Act).

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AUTHORIZED SIGNATURE

DATE OF ATTESTATION

Dr. Elena Vance, Head of Compliance

17.3.2026

PROVIDER

VERIFICATION DATE