Technical Documentation ? RadiologyAssist AI v3.1.0

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Regulation basis: EU AI Act Article 11, Annex IV

1. SYSTEM OVERVIEW

RadiologyAssist AI is a Class IIb medical device AI system MDR 2017/745 and high-risk AI system under EU AI Act Annex III. It analyses chest CT, MRI, and plain X-ray images to identify and classify anomalies, prioritise worklists, and generate structured pre-reports for radiologist review.

Deployed across 8 NeuroVista hospitals; ~1,800 studies processed per day.

2. INTENDED PURPOSE

To assist radiologists in detecting clinically significant findings in thoracic imaging, reduce time-to-diagnosis for critical findings, and support screening programme throughput. Every pre-report is reviewed and signed off by a certified radiologist before delivery to clinicians.

3. ARCHITECTURE AND MODEL DETAILS

Model type: Ensemble ? EfficientNet-V2 classification + U-Net segmentation
Training data: 2.1M annotated imaging studies; 14 European radiology centres
Input: DICOM images CT, MRI, X-ray ? chest focus
Outputs: Finding labels + confidence scores + segmentation masks + pre-report
Inference: On-premises NVIDIA A100 cluster; avg 45s per study

3.1 Detectable findings primary :

- Pulmonary nodule >3mm ? sensitivity 97.1%
- Infiltrate / consolidation ? sensitivity 94.3%
- Pneumothorax ? sensitivity 99.0%
- Pleural effusion ? sensitivity 95.8%
- Cardiomegaly ? sensitivity 93.2%

3.2 Worklist prioritisation:

Critical findings e.g. tension pneumothorax, massive PE : escalated immediately with push notification to on-call radiologist.

4. PERFORMANCE BENCHMARKS

External validation data: RSNA 2024 Chest X-ray Dataset + internal 2025 cohort
AUC any finding : 0.968
Sensitivity critical findings : 98.4%
Specificity: 90.1%
False positive rate per study: 7.2%
Radiologist read time assisted : 2.8 min vs 5.4 min unassisted

5. HUMAN OVERSIGHT

All AI-generated pre-reports are labelled "AI DRAFT ? Radiologist Review Required"
No pre-report is released to clinicians without radiologist digital signature.
Radiologist can reject AI draft and author report de novo at any time.
Automated critical finding alerts require radiologist acknowledgment.

6. CONFORMITY ASSESSMENT

MDR Certificate: CE-NB0124-RADIO-2025-177 Notified Body: BSI Group NB 0086
AI Act Certificate: CE-0123-RADIO-2026-0118 T?V S?D NB 0123
Harmonised standards: ISO 42001, ISO 23894, IEC 62304, ISO 13485
CE marking affixed: 22 October 2025
EU Database: EU-AI-HR-RADIO-2026-0118 registered 15 January 2026