APOLO Medical Multimodal Instruct EU MDR & US CDS Software Conformity Report

Prepared by: Independent Clinical AI Regulatory Analyst
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Scope: Version 1.0 of APOLO Medical Multimodal Instruct (non-CE release)

1. EU MDR 2017/745 Conformity Assessment

1.1 Qualification as Medical Device Software

Under Article 2(1) of EU MDR, software intended for diagnosis or treatment qualifies as a medical device. APOLO, designed to assist clinicians with diagnostic reasoning from medical image descriptions, fits this classification.

1.2 Risk Classification

Rule 11 (Annex VIII) classifies software for diagnosis as Class IIa. APOLO's two-stage model ensures indirect support only, aligning with Class IIa.

1.3 GSPR (Annex I) Compliance Summary

Requirement	Status	Notes
Performance and benefit-risk ratio	✅	High AUC/F1 scores with no direct control of diagnosis
Software lifecycle controls	⚠ Partial	IEC 62304 alignment acknowledged; process documentation pending
Risk management (ISO 14971)	⚠ Partial	Plan in place, but full traceability matrix not submitted

Clinical Evaluation	✅	Supported by evaluations on MIMIC-CXR, ROCO, AREDS datasets
Labelling and IFU	✅	Model card includes clear instructions, intended use, and limitations

1.4 Technical Documentation Status (Annex II)

- ✔ Device description and system overview
- ✔ Design and software implementation overview
- ⚠ Risk file draft in development (requires ISO 14971 traceability)
- ✔ Clinical validation via structured experiments and metrics
- ⚠ Post-market surveillance plan pending implementation
- ❌ Not yet registered in EUDAMED or assigned UDI

2. FDA Clinical Decision Support (CDS) and IMDRF Alignment

2.1 CDS Software Exemption (21 U.S.C. § 360j(o)(1)(E))

APOLO meets the four-part exemption for CDS software:

- Does not directly acquire/analyze raw signals or images
- Displays structured medical information for review
- Supports clinician decision-making without replacing it
- Provides transparent, traceable reasoning (`<think>` tags)

2.2 IMDRF SaMD Categorization

APOLO fits IMDRF SaMD Category II: Software that informs clinical management but does not treat or diagnose directly.

3. Privacy, Security, and Ethical Design

- ✔ Patient data never leaves local environment (Stage 2 never accesses images)
- ✔ GDPR-compliant privacy-by-design architecture
- ✔ Supports clinician control and human-in-the-loop workflow

- ✔ Reasoning traceable for audit and secondary review

4. Final Verdict

Pass with Conditions

APOLO Medical Multimodal Instruct aligns with EU MDR Class IIa and CDS software exemption rules. It is a model-agnostic, privacy-first framework with high explainability. It must, however, complete technical documentation and Notified Body engagement for full CE-marking.

5. Recommendations for Compliance Completion

1. Complete ISO 14971 risk traceability matrix
2. Document IEC 62304-compliant software lifecycle procedures
3. Register UDI and notify EUDAMED
4. Appoint regulatory QMS lead (ISO 13485)
5. Engage a Notified Body for conformity assessment
6. Implement post-market surveillance dashboard and SOP

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