

Instructions for Use — HemoDoctor SaMD (v0.5)

Date: 20250917 | Software version: 0.0.1 | UDI/Version: TBD

Section	Summary
Intended Use / Uso pretendido	CDSS to assist licensed clinicians with CBC interpretation and suggest next diagnostic tests
Device Identification / Identificação	HemoDoctor SaMD; Model/Build: HD-SaMD-001; SW version: 0.0.1; Manufacturer: MedTech Corp
Warnings / Contraindications / Limitations	Automation bias mitigation: Always review underlying rationale; verify abnormal results
Performance Characteristics	See CER-001 and TRP-001: ROC/PR, calibration, decision curve; system latency: < 500ms
Cybersecurity / Segurança Cibernética	SBOM (CycloneDX/SPDX) and VEX provided; update policy and CVD URL included
Data Protection	LGPD-compliant processing; pseudonymization; role-based access; audit trail; data retention: 7 years
Revision Control / Controle de Revisão	Issue date 20250917. For the latest eIFU and SBOM links, visit: https://example.com/updates