

Class IIa Med Device

Edge-AI

120+ Modalities

FHIR R4

CE Electrical

01 — WHO WE ARE

Zoya Technologies LLC is a medical technology company developing Physical AI clinical infrastructure for institutional healthcare deployment. Our flagship product, ZoyeMed 3.0, is a Class IIa regulated autonomous clinical terminal that integrates a 120+ modality sensor array with on-device longitudinal AI inference, clinical decision support, and FHIR R4 interoperability — built specifically for underserved and remote settings where physician presence is unavailable and connectivity is unreliable.

The platform was designed from first principles for exactly the operating conditions this challenge describes: all primary AI inference runs on-device with no cloud dependency; patient data is anonymized at the edge before any transmission; and the system operates reliably where connectivity is intermittent. It connects local communities to specialist care through a Hub-and-Spoke model with remote physician backstop - bridging the gap between rural populations and clinical expertise.

02 — OPERATIONAL EVIDENCE

15 yrs

Continuous clinical AI deployment (India, 2010-present)

9M+

Patient episodes across platform lineage

18,224

PMCF-documented consultations (Mar 2025–Feb 2026)

44 units

Delivered, Mexico institutional programme (up to 300 contracted)

3

Active country deployments Mexico · Colombia · Malaysia

03 — ARCHITECTURE FIT FOR THIS CHALLENGE

- **120+ Sensor Modalities** - 12-lead ECG, biochemistry, haematology, digital stethoscopy, thermal imaging, spirometry, dermatoscopy, urinalysis. Objective physiological ground truth at the point of care.
- **Safety Gate (L2 Amygdala)** - Scores data sufficiency before any inference. Refuses clinical output when inputs are inadequate. The architecture of refusal - critical in unsupervised rural deployment.
- **Edge Inference** - No cloud round-trip required for primary clinical operation. Functions in low- and intermittent-connectivity environments by design.
- **Longitudinal AI (L3 Cortex)** - Tracks patient biomarker trajectories across visits, not single snapshots. Detects adverse trends invisible to single-encounter systems.
- **FHIR R4 Interoperability** - Native integration with hospital information systems. ICD-10/11, SNOMED CT, LOINC, RxNorm terminology mapping. Continuity of care preserved across the care pathway.
- **Governance Layer (L4)** - Per-jurisdiction data residency, consent scope, immutable audit trail. Clinician sign-off required for all consequential actions. Autonomous prescribing architecturally prohibited.

04 — REGULATORY STATUS & RECOGNITION

CE Electrical Certified

NYCE Mexico Certified

CE-MDR (system) In process

CDSCO India In process

PCT Patent Filed 2025–26

WEF / Schwab Foundation Social Entrepreneur of the Year 2020 · UN Innovation Public Appreciation Award 2020 · Bloomberg New Economy Forum Gamechanger 2020 · Frost & Sullivan India Telemedicine 2020