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SAMPLE EXCERPT · 6 OF 28 PAGES

IGR-001

Executive Brief

Interim Governance for High-Stakes Clinical AI

IGR-001 | ISO 14971 | TGA Class IIb | FHIR R4 | MHWA s 28

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SECTION 01

Executive Snapshot

IGR-001 is the Interim Governance Resolution — a deployable oversight layer for clinical AI and software-as-a-medical-device (SaMD) operating in high-stakes clinical environments. It is designed for the operational window between regulatory clearance (CE / TGA / FDA) and mature institutional quality-management-system (QMS) adoption — the gap where most clinical-AI deployments currently sit.

The framework is regulator-traceable: every required control is sourced verbatim to ISO 14971, the TGA SaMD risk-classification rules, the FDA AI/ML transparency criteria, the Mental Health and Wellbeing Act 2022 (Vic) s 28 escalation provisions, and the Charter Act ss 7–8. It is independent: not bound to any single hospital, vendor, or deployment pathway.

This sample excerpts the cover, the executive snapshot, the three-pillar architecture, an IGR-001 v1.3 preview, and the full framework stack table of contents — six of twenty-eight pages.

WHAT THIS DOES

- Encodes the minimum oversight architecture a deployer needs
- Names escalation boundaries, audit-trail discipline, override semantics
- Maps each control to its regulatory anchor — verbatim
- Licensable as a named-use framework instance

WHAT THIS DOES NOT CLAIM

- It is not a substitute for an internal QMS
- It does not replace clinical-governance committees
- It is not regulator certification or endorsement
- It is not legal advice — see Annex B

SECTION 02

The Governance Question

Clinical AI in 2026 has a load-bearing claim that is structurally different from the claim it carried in 2020. The 2020 claim was about accuracy: does the model match the radiologist, the pathologist, the intensivist. The 2026 claim is about high-stakes use: when the model is wrong, when it operates near its uncertainty boundary, when its output triggers an escalation — what happens next?

Three regulatory instruments are converging on this question:

TGA SaMD	Risk-classification by intended use + harm severity. Class IIb = moderate-to-significant harm if the device fails. Software lifecycle expectations explicit.
FDA AI/ML	Transparency criteria for AI-enabled medical devices (2024–2025). Predetermined Change Control Plans (PCCPs). Algorithmic-bias auditing requirements.
MHWA s 28	Victorian involuntary-treatment authority. Where a CDSS supports the decision to invoke s 28, the escalation pathway is no longer a vendor choice — it is a statutory obligation.

The framework gap is not in any single instrument — each is internally coherent. The gap is in the interface between them. A SaMD that has cleared TGA Class IIb still has to be deployed under a hospital QMS, governed by clinical-decision-making law, and operated within human-rights instruments. No single regulator wrote that interface. IGR-001 does.

SECTION 03

Three-Pillar Architecture

IGR-001 organises the oversight layer around three pillars, each anchored to a primary regulatory instrument and instantiated through a named workbook. The pillars are interlocking, not sequential — a CDSS that passes one and fails another is not deployable.

PILLAR

01 · Risk

ISO 14971

Hazard identification, control adequacy, residual-risk acceptance, post-market surveillance. The risk file is the load-bearing artifact — every clinical control traces back to it.

FX-RISK-MATRIX-001
INSTRUMENT

PILLAR

02 · Audit

G1–G5 GATES

Five admission gates a CDSS must clear before any clinical use: evidence sufficiency, alignment with intended use, escalation discipline, audit-trail completeness, oversight reach.

FX-GOV-SCORECARD-001
INSTRUMENT

PILLAR

03 · Oversight

MHWA S 28 + CHARTER

Where the CDSS output influences statutory decisions — involuntary treatment, restraint, restrictive practice — the oversight layer ceases to be optional. Charter Act ss 7–8 + CRPD Arts 5/12/14.

FX-OVERSIGHT-MATRIX-001
INSTRUMENT

The three pillars do not stack — they bind. A CDSS that clears risk but fails audit is not 'partially deployable'. It is not deployable.

SECTION 04

IGR-001 v1.3 — Preview

The interim governance resolution, in canonical surface form.

§1 Scope

This Resolution governs the operational deployment of clinical-AI and SaMD systems within high-stakes clinical environments, including but not limited to assessment, triage, restraint, restrictive practice, and involuntary-treatment decision support.

§2 Independent Architecture

The oversight layer constituted by this Resolution shall not be tied to a single hospital, vendor, deployment pathway, or product. Conflicts of interest at any layer of the architecture invalidate the layer.

§3 Pillar Triad

The Resolution binds three pillars — Risk (ISO 14971), Audit (G1–G5 admission gates), Oversight (MHWA s 28 + Charter overlay). A system clearing fewer than three pillars is not deployable under this framework.

§4 Named-Use Licence

Each deployer of this Resolution shall hold a named-use licence specifying the CDSS asset, the deployment scope, the responsible clinical lead, and the governance review cadence. Licence is not transferable.

§5 Disclosure-via-Changelog

Where any controlling regulatory instrument is updated, the corresponding clause of this Resolution shall be updated through a sealed changelog entry. Silent revision is incompatible with the Resolution.

SEALED · Sample shows §§1–5 of 14. Full instrument available under Tier 1+ licence.

SECTION 05

Full Framework Stack

Ten components — the complete table of contents of the framework.

01 **Executive Snapshot**
The governance thesis on one page. Why high-stakes clinical AI needs an independent oversight architecture before deployment, not after.

02 **The Governance Question**
Why "high-stakes use" — not initial accuracy — is the load-bearing claim. The FDA / TGA / MHWA convergence.

03 **The Three-Pillar Architecture**
Risk (ISO 14971) · Audit (G1–G5 gates) · Oversight (MHWA s 28 + Charter).

04 **IGR-001 — Interim Governance Resolution**
The flagship instrument. Fourteen clauses, three sealing annexes.

05 **ISO 14971 Alignment Matrix**
Risk-management lifecycle mapped to the CDSS pipeline. Editable for Tier 2+.

06 **G1–G5 Admission Gates**
The FX-GOV-SCORECARD-001 workbook. Evidence, alignment, escalation, audit, oversight.

07 **TGA Class IIb Pre-Submission Pathway**
SaMD risk-classification logic, software lifecycle expectations, regulator-meeting structure.

08 **FHIR R4 + CDS Hooks Integration**
Hook taxonomy, latency budgets, fallback semantics, audit-event spec.

09 **MHWA s 28 + Charter Overlay**
Where clinical AI intersects involuntary treatment and human-rights instruments.

10 **References & Changelog**
Every load-bearing requirement sourced verbatim. Disclosure-via-changelog discipline.

Full framework available through engagement at Fx CDSS.

Tier 1 · Governance Diagnostic — USD 2,500. Tier 1+ adds the IGR-001 named-use licence — USD 4,500.

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