Regulatory Requirements

Medical Devices | Readiness Checklist

Device / role: _____ Reviewer / date: _____

Mark Ready, Gap or N/A. Reference evidence and justify N/A decisions.

1. Applicability and responsibility

- ☐ Define intended purpose, claims, device configuration and target markets.
- ☐ Document classification, organization roles and applicability rationale.
- ☐ Identify current regulations, guidance and relevant standards by market.

2. Technical documentation

- ☐ Check device description, design records and evidence against current configuration.
- ☐ Connect requirements, risk controls, verification and validation records.
- ☐ Identify incomplete records and inconsistencies across the evidence package.

3. Clinical and performance evidence

- ☐ Check evidence supports the intended purpose, population and claimed performance.
- ☐ Assess data relevance and gaps for the applicable regulatory framework.
- ☐ Document the rationale for additional data or investigations where needed.

4. Risk management and testing

- ☐ Connect hazards, risk controls, testing and residual risk evaluations.
- ☐ Review test configurations, acceptance criteria, deviations and conclusions.
- ☐ Check applicable standard editions and market recognition or designation.

5. Labeling, IFU and claims

- ☐ Compare labels, IFU and promotional claims with evidence and authorized scope.
- ☐ Check applicable warnings, limitations, symbols, language and identification.
- ☐ Assess changes in claims, use environments or software functions.

6. Gap closure and evidence ownership

- ☐ Separate mandatory obligations from guidance and implementation choices.
- ☐ Assign priority gaps, evidence references, owners and completion dates.
- ☐ Define review points and update evidence when product or requirements change.

Priority gap / evidence reference / owner / target date:

Planning aid, not a legal opinion or an authorization decision. Confirm requirements for the device, organization and each target market using current official sources. Reviewed October 13, 2026.