Global Regulatory Strategy

Medical Devices | Readiness Checklist

Device / role: _____ Reviewer / date: _____

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

1. Product, claims and responsibilities

- ☐ Define intended use, users, indications, functions and proposed claims.
- ☐ Identify product variants, accessories and relevant software functions.
- ☐ Confirm the legal manufacturer and responsibilities of other involved parties.

2. Target markets and pathways

- ☐ Prioritize markets against commercial objectives and product maturity.
- ☐ Record classification and pathway rationale for each agreed jurisdiction.
- ☐ Flag assumptions needing confirmation or an appropriate authority interaction.

3. Evidence and standards

- ☐ Inventory existing technical, performance, software and clinical evidence.
- ☐ Assess applicable standards and market recognition or designation.
- ☐ Identify evidence gaps, reusable records and market-specific adaptations.

4. Readiness and local obligations

- ☐ Check relevant QMS evidence, labeling and technical documentation needs.
- ☐ Identify applicable local representation, registration or licensing duties.
- ☐ Confirm the device and scope match any existing authorizations relied upon.

5. Submission scope and coordination

- ☐ Define authoring, review, assembly, filing and authority response scope.
- ☐ Assign technical inputs, document owners, review points and final approvals.
- ☐ Plan external testing, studies, translations and third-party fees separately.

6. Roadmap and change review

- ☐ Sequence work by dependencies; distinguish project time from authority review.
- ☐ Track priority gaps, owners and evidence needed for the next decision.
- ☐ Reassess strategy when design, claims, markets or manufacturer roles 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 12, 2026.