Elexes

Regulatory Checklist for Physical Therapy Medical Devices (FDA + CE)

Device Classification & Strategy:

- Device intended use clearly defined
- FDA classification determined (Class I, II, or wellness)
- CE marking or UKCA regulatory path identified

Testing Requirements:

- Electrical safety and EMC testing plan in place (e.g., IEC 60601)
- Biocompatibility assessment completed (if skin contact)
- Software validation (if digital or AI-based)
- Usability testing for patient-facing interfaces

Documentation & Submission:

- QMS established as per ISO 13485 / 21 CFR Part 820
- Risk management file developed (ISO 14971)
- 510(k) or CE Technical File drafted
- Labeling compliant with FDA or MDR/IVDR

Innovation Readiness:

- Unique features assessed for regulatory implications
- Real-world evidence or clinical support (if needed)
- Cybersecurity (if connected) and SBOM documentation prepared