Elexes

IVD Certification Submission Checklist

Device Classification & Intended Use

- Intended use clearly defined with target population and specimen type
- Device classification confirmed per IVDR, FDA, or local authority
- Justification for classification and conformity assessment route documented

Performance Evaluation

- Scientific validity supported with peer-reviewed literature
- Analytical performance study protocols and results available
- Clinical performance study plans and data compiled (if required)
- PMPF (Post-Market Performance Follow-up) plan developed

Technical Documentation

- IVDR-compliant Technical File or FDA 510(k) dossier drafted
- GSPR checklist (EU) or FDA Submission Checklist completed
- Labeling, UDI, IFUs aligned with applicable regulatory format
- Traceability from requirements to test reports maintained

Risk Management & Cybersecurity

- Risk management file per ISO 14971 updated
- Usability engineering file included for applicable devices
- Cybersecurity documentation completed (for software/connected IVDs)
- Hazard and residual risk analysis documented and linked to mitigations

QMS & Regulatory Compliance

- ISO 13485 certification or equivalent QMS documentation available
- Internal audits and management reviews conducted
- Regulatory strategy and timeline finalized
- Pre-submission or consultation meeting with authority completed (if applicable)

Submission Preparedness

- Submission documents formatted and reviewed for completeness
- Summary of Safety and Performance (SSP) or Executive Summary written
- Authorized representative appointed (EU/UK)
- Submission portal access tested and account credentials validated