Elexes

MR Device Compliance Checklist

Regulatory & Classification

- Confirm device classification under MDR/FDA/other applicable regulatory authorities
- Identify applicable MR-specific standards (e.g., IEC 60601-2-33, ASTM F2503)
- Define regulatory pathway (510(k), CE Marking, etc.)

Risk & Safety

- Perform risk analysis (ISO 14971)
- Verify MR safety labeling: MR Safe, MR Conditional, MR Unsafe (ASTM F2503 terminology)
- Validate device performance in MR environment (magnet, RF, gradients field)

Documentation & Testing

- Maintain Technical File/DHF with MR validations
- Complete biocompatibility, EMC, and usability testing
- Provide verification & validation reports specific to MR safety

Labeling & IFU

- Include MR safety symbols (ISO 15223-1, ASTM F2503)
- Provide clear MR usage instructions and warnings in IFU
- Ensure compliance with region-specific labeling requirements

QMS & Post-Market

- Operate under ISO 13485-compliant QMS
- Set up Post-Market Surveillance (PMS) & vigilance reporting
- Continuously update risk management with post-market data