Harmonised Standards Compliance Checklist for EU MDR & IVDR

1. Device Classification Context

- Determine device classification in accordance with EU MDR Annex VIII (Class I, IIa, IIb, or III) or IVDR Annex VIII (Class A, B, C, or D).
- Classification determines the conformity assessment procedure, applicable standards, and involvement of a Notified Body.

2. Identify Applicable Harmonised Standards

- Consult the EU's Official Journal
- Verify alignment with General Safety and Performance Requirements (GSPRs)

3. Implementation & Evidence Collection

- Verify implementation of each clause of the applicable standard
- Document objective evidence (test reports, design documents, protocols, verification etc.)

4. Include in Technical Documentation

- Annex Z mapping included
- Relevant standards referenced in Design Dossier / STED

5. When Harmonised Standards Are Not Available

- Justify alternate standards or methodologies
- Document risk-based rationale