Wearable Medical Device Compliance Checklist – Global Standards & Launch Readiness

Design & Development Stage

- Device classification and intended use documented
- Design controls implemented (FDA 21 CFR 820.30 / ISO 13485 Clause 7.3)
- Risk management file created (per ISO 14971)
- Human factors & usability testing completed (per IEC 62366)
- Data privacy and cybersecurity reviewed

Software Compliance (if applicable)

- Software safety class determined (per IEC 62304)
- Verification and validation activities documented
- Source code and version control in place

Regulatory & Market Access

- Technical documentation prepared for CE marking (Annex I & II of EU MDR)
- FDA pathway determined (510(k), De Novo, Class I exemption)
- Labeling and IFU aligned with UDI and MDR/FDA requirements
- Authorized Representative or Importer (if selling in EU/UK) identified

Post-Market Compliance

- Post-market surveillance (PMS) plan prepared
- Vigilance and reporting SOPs defined
- Cybersecurity updates tracked and documented