

Wearable Medical Device Compliance Checklist

- Clearly define intended use and medical claims
- Determine device classification across target markets
- Identify applicable regulatory pathways (FDA, MDR, TGA, Health Canada)
- Implement design controls and risk management (ISO 14971)
- Validate software, connectivity, and cybersecurity controls
- Data privacy and data protection compliance (e.g., GDPR, HIPAA, where applicable)
- Battery safety and electrical safety testing (IEC 60601 / IEC 62133 where applicable)
- Conduct usability and human factors engineering studies
- Generate appropriate clinical and performance evidence
- Ensure biocompatibility for prolonged or repeated skin contact
- Prepare compliant labeling and IFU content
- Establish post-market surveillance and vigilance processes