

Wearable medical devices vs Hospital Equipment Comparison Checklist

Purpose & Use

- Wearable: Continuous or remote monitoring supports early detection and patient self-management.
- Hospital Equipment: Diagnostic, therapeutic, or procedural use

Accuracy & Reliability

- Wearable: Good for trends; variable precision
- Hospital Equipment: High precision validated performance, and strong and clinical reliability

Regulatory Requirements

- Wearable: Often regulated as medical devices depending on intended use and claims
- Hospital Equipment: Strict regulatory scrutiny, mandatory conformity assessment and certification

Risk Classification

- Wearable: Often lower risk classification (e.g., Class I or II depending on function and claims).
- Hospital Equipment: Frequently moderate to high risk classification (e.g., Class IIb or III depending on intended use).

Integration

- Wearable: Needs connectivity with apps/EHRs
- Hospital Equipment: Designed for integration into hospital IT systems and clinical workflows.

Clinical Validation:

- Wearable: Rely on usability studies, performance validation, and limited clinical data depending on claims.
- Hospital Equipment: Requires comprehensive verification, validation, and often extensive clinical evaluation.

Cost & Procurement

- Wearable: Lower unit cost; consumer or enterprise pricing
- Hospital Equipment: High capital investment; complex purchasing

Maintenance & Support

- Wearable: Software updates; limited servicing; shorter product lifecycle.
- Hospital Equipment: Preventive maintenance, regular calibration, technical service and lifecycle management required.

Market Entry

- Wearable: Faster adoption in consumer health
- Hospital Equipment: Longer sales cycles with institutional approval