**Engagement ID**: MD-003 **Engagement Name**: Advanced Patient Monitoring Device Development **Client Name**: BioMedTech Solutions

**1. Purpose**

This document outlines the **design and development framework** for a **new medical device**, ensuring partial compliance (60%) with **ISO 13485, IEC 62304, and FDA 21 CFR Part 820**. It establishes the foundation for validation and risk assessment activities.

**2. Scope**

This plan applies to the development of a **wearable patient monitoring device**, integrating **hardware, software, and real-time analytics**.

**3. Risk Management**

✔ **Risk Management Plan** aligned with **ISO 14971** for medical device risk classification. ✔ **Early risk identification** at **design input and prototyping** stages.

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**4. Design and Development Stages**

1️⃣ **Planning & Risk Assessment** – Define scope, compliance measures, and risk factors. 2️⃣ **Concept Design & Prototyping** – Validate feasibility through initial testing. 3️⃣ **Design Input & Specification Development** – Establish user and regulatory requirements. 4️⃣ **Software & Hardware Development** – Ensure system integration with medical data processing. 5️⃣ **Partial Verification & Validation (V&V)** – Conduct intermediate testing with **limited clinical usability studies**. 6️⃣ **Manufacturing Feasibility Assessment** – Validate design transfer for production readiness. 7️⃣ **Initial Post-Market Surveillance Considerations** – Define basic monitoring strategies post-launch.

**5. Design Requirements Development**

**N/A**

**6. Design Verification & Validation (V&V)**

🔹 **Functional and software verification** (limited unit testing, integration testing). 🔹 **Preliminary usability evaluations** (simulated patient interaction studies). 🔹 **Third-party compliance evaluation** scheduled but not yet completed.

📌 **Note:** Full regulatory validation will require additional testing phases and refinements.

**7. Design Transfer Strategy**

📌 **Transition to manufacturing facility** based on preliminary **design readiness assessments**. 📌 **Limited deployment testing for hardware-software integration** before final transfer.

**8. Traceability & Documentation Status**

✔ **Requirement Traceability Matrix (RTM) under development**. ✔ **Software of Unknown Provenance (SOUP) logging initiated** but **not fully implemented**.

**9. Problem Resolution Workflow**

🔹 **Basic CAPA strategy defined** (corrective and preventive actions). 🔹 **Defect reporting mechanisms in place** but require regulatory framework alignment.

**10. Resources & Development Tools**

📌 **Technology stack & validation tools partially integrated**:

* **JIRA** – Limited defect tracking and validation records.
* **Automated Testing Frameworks** – Preliminary software validation modules.

**Final Notes & Change Control**

🔄 **Document Change History** – Logged but **awaiting completion of full review cycle**. 📌 **Next Validation Phase** – Scheduled refinements to achieve **80% validation compliance**.