**Medical Device Design and Development Plan**

**Engagement ID**: MD-003 **Engagement Name**: VitalSense Medical Device Development **Client Name**: MedInnovate Ltd

**1. Purpose**

This document establishes the **initial framework** for the design and development of the **VitalSense Medical Device**, a next-generation healthcare solution. The plan will ensure partial alignment with **ISO 13485, IEC 62304, and FDA 21 CFR Part 820**, with further validation required to achieve full compliance.

**Outstanding Gaps**

* Risk mitigation documentation needs finalization.
* Compliance validation checklist incomplete.
* Prototype testing phase pending approval.

**2. Scope**

This plan applies to **both software-integrated and hardware-based solutions**, with a focus on **real-time patient monitoring**.

**Key Scope Considerations**

✅ **Legacy Software Inclusion:** *Requires review* ✅ **Lifecycle Model:** *Yet to be determined* ✅ **Review Cycle:** *TBD - Regulatory approval pending*

**3. Risk Management**

**Outstanding Gaps**

🚧 **Risk classification framework incomplete** 🚧 **ISO 14971 alignment needs refinement**

✔ **Identified Risk Areas:**

* Clinical data accuracy concerns.
* Cybersecurity threats in patient data storage.
* Manufacturing process inefficiencies affecting device performance.

**4. Design and Development Stages**

1️⃣ **Planning & Initial Risk Management** – Define scope and development risks. 2️⃣ **Design Input Gathering** – Align user needs with technical specifications (**Incomplete**) 3️⃣ **Prototyping & Testing Preparation** – Validate early-stage feasibility (**Pending approval**) 4️⃣ **Design Verification & Validation (V&V)** – Initial compliance testing (**Partially outlined**) 5️⃣ **Manufacturing Transfer & Scalability Review** – Assess production feasibility (**TBD**) 6️⃣ **Post-Market Surveillance Framework** – Establish monitoring strategy (**Needs further definition**)

**5. Design Requirements Development**

✔ **Basic system requirements identified** ✔ **Initial regulatory traceability matrix drafted** 🚧 **Software testing methodology yet to be defined** 🚧 **Risk control mapping incomplete**

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

✔ **System integration testing planned** ✔ **Clinical usability testing outlined** 🚧 **Third-party compliance testing pending** 🚧 **Automated validation frameworks need assessment**

**7. Design Transfer Process**

✔ **Manufacturing site evaluation initiated** 🚧 **Material selection framework incomplete** 🚧 **Production validation still in early-stage discussions**

**8. Traceability & Documentation Status**

✔ **Preliminary tracking established** 🚧 **SOUP methodology review required**

**9. Problem Resolution Workflow**

✔ **Basic CAPA framework drafted** 🚧 **Regulatory reporting mechanisms incomplete**

**10. Resources & Development Tools**

✔ **Project management tools identified** 🚧 **Testing and validation software selection pending**