**Design Verification Report**

**VER250627a**

1. **Background:**

Verification of current release candidate to support PR250314a

1. **Objective (project reference, if any):**

**Verify release candidate**

1. **Design [verification/validation] performed by:**

*PG*

1. **Product Name**

**VISI**

1. **Verification/Validation no. VER/VALyymmdda)** VER250627a
2. **Methods**: (ISO 13485:2016 7.3.6): **If Visi-Download, also modify 3.321 Visi-Download verification. See SSI-QF-10R Design Verification/validation Protocol**

**Acceptance criteria (**ISO 13485:2016 7.3.6)**:**

**Check for presence of new code**

**Suitable objective evidence (**ISO 13485:2016 7.3.6)**:**

**Code present**

**Statistical techniques with rationale for sample size (**ISO 13485:2016 7.3.6)**:**

**n/a**

**Does the intended use of a device require that it be connected to or have an interface with other medical device (yes/no) (**ISO 13485:2016 7.3.6)**:**

**Not required**

**If yes, how is verification performed?:**

**n/a**

1. **If this is verifying a software problem resolution (BS EN 62304:2006+A1:2015), verify to determine whether:**
2. The problem has been solved and the Problem Report has been closed: Y
3. Any adverse trends have been reversed: n/a
4. Change requests have been implemented in the software; Y
5. Any additional problem has been introduced: n/a

**Results: (pass/fail) (**ISO 13485:2016 7.3.6): **pass**

[Summarize the results or data obtained from the verification/validation activity. Raw data, graphs, drawings, photographs, or other detailed objective evidence should be included as attachments, as appropriate.]

1. **Deviations:**

*n/a*

1. **Analysis** (if/as required):

**n/a**

1. **Conclusions:** (ISO 13485:2016 7.3.6)**:**

*onwaords*

1. **Attachments** (if any)**:**

[Provide list of attachments]

1. **Report sign off and any other approvals**

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| --- | --- | --- |
| **Name + Title** | **Signature** | **Date** |
| *Gwilym Davies, CEO* | **GJGD** | **27/06/2025** |
| *Paul Gladding, Systems Manager* | **PG** | **27/06/2025** |
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**Store this document within the Technical Documentation.**