**Design** Choose an item. **Report**

**[Add Report Title]**

1. **Background:**

[Provide background information as necessary to explain the verification/ validation activities conducted. Include traceability to specific design inputs and/or user needs.]

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

Click or tap here to enter text.

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

[Indicate who performed the verification/ validation activity, including any outside testing facility.]

1. **Product Name**

Click or tap here to enter text.

1. **Verification/Validation no. VER/VALyymmdda)** Click or tap here to enter text.
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)**:**

Click or tap here to enter text.

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

Click or tap here to enter text.

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

Click or tap here to enter text.

**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)**:**

Click or tap here to enter text.

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

Click or tap here to enter text.

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 or N
3. Any adverse trends have been reversed: Y or N
4. Change requests have been implemented in the software; Y or N
5. Any additional problem has been introduced: Y or N

**Results: (pass/fail) (**ISO 13485:2016 7.3.6):Click or tap here to enter text.

[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:**

[Summarize any protocol deviations and their impact on the results.]

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

Click or tap here to enter text.

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

Click or tap here to enter text.

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

[Provide list of attachments]

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

|  |  |  |
| --- | --- | --- |
| **Name + Title** | **Signature** | **Date** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap to enter a date. |
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