

# Design Verification Protocol

Use this template to protocol verifying [device\_name] design outputs against design inputs.

## Template Metadata

Field	Details
Category	Medical Devices
Owner	[Team or owner]
Version	[Version number]
Effective Date	[Date]
Review Cycle	[Monthly / Quarterly / Annual / Event-based]
Status	[Draft / In Review / Approved]

## Purpose

State the device, design phase, and objective for verifying design outputs against approved inputs.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

## Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Scope

Define models, configurations, software versions, accessories, environments, and exclusions.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

## Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Referenced Inputs

List design input IDs, risk controls, standards, and performance requirements covered by the protocol.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

## Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Test Methods

Describe bench, software, inspection, analysis, and standards-based methods with traceability.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

## Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Samples and Equipment

Specify sample build status, lot or serial numbers, fixtures, calibrated equipment, and prerequisites.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

## Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Acceptance Criteria

Define pass/fail criteria for each requirement and risk control verification.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

## Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Deviations and Report

Explain deviation handling, retest rules, data review, and final verification report approval. Use design-control terminology and include traceability tables.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

## Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Review and Signoff

Document review conclusions, approvals, unresolved items, and next review date.

Role	Name	Date	Notes
Preparer	[Name]	[Date]	[Notes]
Reviewer	[Name]	[Date]	[Notes]
Approver	[Name]	[Date]	[Notes]