



Test Protocol for Medical Devices

Template Provided by Element Materials Technology

The information provided in this template is for general informational purposes only

Approvals	Name	Signature	Date
R&D Engineer			
Test Engineer			
Management			

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1. Scope

The scope of this study applies to [Company Name] [Device Name] [type of] testing. Briefly describe what the study entails and which device the test protocol is for.

2. Purpose

The purpose of this study is to define the test methods used to demonstrate the [Property] of the finished [Device Name] product when [Specify Conditions].

Describe the objective of the test and the data that will be used, give background information in the background section.

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4 Test Samples

This section should include the following subsections:

Sample Identification

Sample Size and Rationale

Sample Traceability or unique project specific identification

Worst Case Analysis

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Table 4 Example Pre-test Operations
Test

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Example load selection flowchart for fatigue parameters

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10 References

Create bibliography of all pertinent references.

11. Revision History

Revision No	Revision Description	Approved By	ECN #	Effective Date