Elexes

ISO 10993-12 Sample Preparation Checklist

✓ **Confirm Device Configuration**

Ensure the test article represents the final, clinically used configuration

✓ **Define Contact Type & Duration**

Align sample preparation with the device's biological contact category and exposure duration per ISO 10993-1

✓ **Select Appropriate Test Samples**

Include worst-case materials, manufacturing variants, and high-exposure surfaces

✓ **Validate Sample Size & Surface Area**

Calculate and document the surface area-to-volume ratio as required by ISO 10993-12

✓ **Choose Extraction Solvents**

Use solvents compatible with device materials and relevant to clinical use, ensuring no degradation, swelling, or particulate generation

✓ **Set Extraction Conditions**

Document time, temperature, agitation, and rationale

✓ **Use Correct Reference Materials**

Include stable, well-characterized, traceable reference standards

✓ **Apply Clean, Controlled Handling**

Prevent contamination during cutting, cleaning, or sterilization handling steps

✓ **Record Sterilization & Pretreatment**

Capture cycle parameters and justify any deviations

✓ **Document Justifications for Waivers/Reductions**

Provide scientific rationale if sample prep steps are minimized or omitted