



Apply bar code  
Lab Number

### Ethylene Oxide Residual Testing Extraction Specifics

COMPANY: \_\_\_\_\_

CONTACT: \_\_\_\_\_

LAB NUMBER: \_\_\_\_\_

#### AERATION

**Yes** (Please perform ambient aeration as described below)

**No** (Not required/already completed)  
Please Specify:

\_\_\_\_\_  
\_\_\_\_\_

**Single Device**

**Multi-Component Device** (i.e. Catheter with Stent)

If requiring more than one of the extraction categories below, please specify in notes. List all components, and delineate which have permanent, prolonged or limited use.

**Extract entire device**

**Extract specified portion of device** (Please specify below and attach a diagram where available)

\_\_\_\_\_  
\_\_\_\_\_

#### EXTRACTION CATEGORIES

**Limited Use** (<24 hours exposure)

**Prolonged Use** (24 hrs – 30 days exposure) perform simulated use, exhaustive extraction

**Permanent Use** (30+ days exposure) perform simulated use, exhaustive extraction

Extraction Type:  Immersion  Fluid Path

Extraction Time: \_\_\_\_\_, or  24 hours ± 1 hour  
(Minimum extraction time 1 hour, prolonged and permanent 24 hours ± 1 hour)

Extraction Temperature:  20 – 25°C  35 – 39°C

**Analyze Individually**  **Pool Devices** (number pooled) \_\_\_\_\_

**Report TCL: Surface Area (cm<sup>2</sup>)** \_\_\_\_\_

NOTES: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

\*\*Exhaustive Extraction: Extraction until the amount of EO or ECH in a subsequent extraction is less than 10% of that detected in the first extraction, or until there is no analytically significant increase in the cumulative residue levels detected". ANSI/AAMI/ISO 10993-7:200

NAME: \_\_\_\_\_ DATE: \_\_\_\_\_

**ANSI/AAMI/ISO 10993-7:2008 requires that samples be shipped by overnight delivery on dry ice and dry ice must remain until opened in the laboratory.**