



Apply bar code  
Lab Number

Ethylene Oxide Residual Extraction Specifics Form

SPONSOR: \_\_\_\_\_  
CONTACT: \_\_\_\_\_  
LAB NUMBER: \_\_\_\_\_

AERATION

- Yes (Performed by NLI)
- No (Not required/already completed)
- Please Specify: \_\_\_\_\_

- Single Device
- Or
- 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 – delineate which have permanent, prolonged or limited use.**  
**Please attach a diagram where available.**

EXTRACTION CATEGORIES

- Limited Use (<24 hours exposure)  
Extraction Type:  Immersion  Fluid Path  
Extraction Time: \_\_\_\_\_
- Simulated Use (Usually 3x the expected exposure)  
Extraction Time: \_\_\_\_\_
- 24 hr Extraction  
Extraction Temperature:  20 – 25°C  35 – 39°C
- Prolonged Use (24 hrs – 30 days exposure):  
Extraction Type:  Immersion  Fluid Path  
Extraction Time:  24 hr Single Extraction  Exhaustive (24hr increments)  
Extraction Temperature:  20 – 25°C  35 – 39°C
- Permanent Use (30+ days exposure):  
Extraction Type:  Immersion  \_\_\_\_\_  
Extraction Time:  Exhaustive (24hr increments)  
Extraction Temperature:  35 – 39°C
- Analyze Individually  Pool Devices (number pooled) \_\_\_\_\_  
For one result

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

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

\*\*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 10993-7:2008