



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:

SAMPLE DETAILS

- Single Device**
- Multi-Component Device** (i.e., Catheter with Stent)
(when multiple extraction categories are selected, specify components for each category)
- Device intended for adult use** **Device intended for pediatric/neonate 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 (cm²) _____

Pictures Included _____

NOTES: _____

APPROVED BY: _____ DATE: _____

Study Director: Document confirmation/source of parameters when form is not signed by sponsor.

"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.

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.