

Ethylene Oxide Residual Extraction Specifics Form

“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.

Please attach a diagram if available.

Residual Extraction Specifics	Yes/No
Single Device	
Multi-Component Device	
Analyze Individually	
Composite Samples	

Which one of the categories below best describes your product?

Category	Specifics
<p><u>Limited Use (< 24 hour exposure)</u></p> <ol style="list-style-type: none"> 1. Immersion <u>or</u> Fluid Path Extraction 2. Simulated Use (~ 3x the expected exposure)? 3. 24 Extraction at 20-25°C <u>or</u> 35-39°C 	
<p><u>Prolonged Use (24 hrs – 30 days exposure)</u></p> <ol style="list-style-type: none"> 1. Immersion <u>or</u> Fluid Path Extraction 2. Temperature at 20-25°C <u>or</u> 35-39°C 	
<p><u>Permanent Use (30+ days exposure)</u></p> <ol style="list-style-type: none"> 1. Immersion <u>or</u> other 2. Temperature at 35-39°C 	

If requiring more than one of the extraction categories below, please specify below. Please list all components that are to be tested/extracted.

** If tolerable contact limits are needed, please provide the device (s) area in cm².