

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 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
Limited Use (<24 hour exposure) <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 20-20° C <u>or</u> 39-39° C 	
Prolonged Use (24 hrs ~ 30 days exposure) <ol style="list-style-type: none"> 1. Immersion <u>or</u> Fluid Path Extraction 2. Temperature at 20-25° C <u>or</u> 39-39° C 	
Permanent Use (30+ days exposure) <ol style="list-style-type: none"> 1. Immersion <u>or</u> other 2. Temperature at 39-39° 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 needed, please provide the device(s) area in cm².