SPONSOR: ________________________________________________________________

CONTACT: ________________________________________________________________

CONTACT EMAIL: __________________________________________________________

CONTACT PHONE #: ________________________________________________________

DEVICE DESCRIPTION: _____________________________________________________

Please complete the information below per device requirement

STORAGE CONDITIONS: ☐ Freezer ☐ Ambient

RESIDUALS FOR ANALYSIS: ☐ Ethylene Oxide ☐ Ethylene Chlorohydrin ☐ Ethylene Glycol

EXTRACTION CATEGORIES
☐ Limited Exposure (<24 hours exposure):
  Extraction Type: ☐ Immersion ☐ Fluid Path
  Extraction Time: ☐ 24 hr Extraction ☐ _____ hr Extraction
  Extraction Temperature: ☐ Ambient ☐ 37 ± 2°C ☐ Other ( °C)
  Extraction Media: ☐ Water ☐ Other ( )

☐ Prolonged Exposure (24 hrs – 30 days exposure):
  Extraction Type: ☐ Immersion ☐ Fluid Path
  Extraction Time: ☐ Exhaustive Extraction (24hr increments)* ☐ _____ hr Extraction
  Extraction Temperature: ☐ Ambient ☐ 37 ± 2°C ☐ Other ( °C)
  Extraction Media: ☐ Water ☐ Other ( )

☐ Permanent Contact (30+ days exposure):
  Extraction Type: ☐ Immersion ☐ Fluid Path
  Extraction Time: ☐ Exhaustive Extraction (24hr increments)* ☐ _____ hr Extraction
  Extraction Temperature: ☐ Ambient ☐ 37 ± 2°C ☐ Other ( °C)
  Extraction Media: ☐ Water ☐ Other ( )

TESTING GUIDELINES
    Does the device require Tolerable Contact Limit? ☐ Yes or ☐ No
    Device category: ☐ Surface contacting ☐ Implant ☐ Externally communicating ☐ No direct patient contact
    ☐ ANSI/AAMI/ISO 10993-7: 1995 Biological evaluation of medical devices- Part 7 Ethylene oxide sterilization residuals
    ☐ Other ________________________________________________________________

PORTION OF THE DEVICE TO BE TESTED: _______________________________________

PORTION OF THE DEVICE WITH PATIENT CONTACT: ______________________________

NOTES:
______________________________________________________________
______________________________________________________________
______________________________________________________________

SIGNATURE: ___________________________ DATE: __________________________

*"Exhaustive Extraction ANSI/AAMI/ISO 10993-7: Extraction until the amount of residual 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". Per study 2009-GMP-124, Ethox defines analytically insignificant as: (1) the amount of residue is less than the maximum Average Daily Dose (ADD) for the residue being measured as outlined in ANSI/AAMI/ISO 10993-7: 1995 or 2008 with at least three 24 Hr extraction steps to establish a downward trend OR (2) the amount of residue is less than the limit of quantitation (LOQ) for the GC instrument.