eurofins | Medical Device Services

Ethylene Oxide (EO) Residuals Testing

Medical devices sterilised with Ethylene Oxide gas must be tested to ensure any residual sterilant or degradation byproducts are below limits that may pose a toxicological risk to the end users. Many factors can impact the levels of Ethylene Oxide Residuals following sterilisation, such as packaging type, material of components, sterilisation cycle parameters and load density, thus it can be difficult to predict when a product would be safe for release to the public.

Consequently, it is required by regulatory bodies, that medical devices cannot be released until testing is performed and the quantities of these residuals confirmed. Failing to provide proof of the completion of such testing can delay the launch of your medical device, and create supply chain issues for the manufacturer.

Eurofins Medical Device Testing's network of Laboratories offers Ethylene Oxide Residuals Testing to provide clients with one source for all necessary residual and sterility tests on a medical device. Our team has extensive experience in testing for Ethylene Oxide Residuals and working with clients to navigate the ISO 10993-7 testing requirements.

Your company will have direct communication with our laboratory to guarantee your medical device is tested to the appropriate standards.

Choose Eurofins Medical Device Testing to help you:

- Utilise one source for sterility testing and residuals testing.
- Navigate ISO 10993-7 to determine appropriate specifications for your product.
- Determine appropriate extraction methods and testing of Ethylene Oxide Residuals.
- Use platform methods to test most products quickly and efficiently with little time needed for establishment.
- Develop and validate Ethylene Oxide Residual methods for products that require specialised treatment, have unique specifications, or present interferences with routine residual levels.
- Perform Ethylene Oxide Residual testing for validation of sterilisation cycle and products.
- Ensure residuals from your Ethylene Oxide Sterilisation are not harmful to a patient.

Testing Services

Biocompatibility & Toxicology • Cleaning & Reprocessing Validations
Chemical & Physical Analysis • Distribution & Package Integrity
Performance Testing • Human Factors & Usability • Microbiology & Sterility Mechanical & Functionality • Viral Safety

Flexible Models

Fee For Service (FFS)
Full-Time-Equivalent (FTE)
PSS Insourcing Solutions®

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