

 **Nelson Labs**[®]
A Sotera Health company

 **Sterigenics**[®]
A Sotera Health company

Wiesbaden, Germany Microbiological Lab Testing Services

for pharmaceutical products, pharmaceutical packaging systems and medical devices.



Safeguarding Global Health.

- with every test we complete.

www.nelsonlabs.com
www.sterigenics.com



Introduction

Sterigenics Germany opened its doors in Wiesbaden, Germany in 2006 offering a few tests supporting sterility . Since then, its laboratory division has grown to become a strong partner in testing solutions. To anticipate the growing testing demand in the medical device and pharmaceutical packaging industries, new space was acquired, and the laboratory now goes to market as Nelson Labs.

Part of a Global Network

As a Nelson Labs company, the Wiesbaden lab is part of a global provider of more than 800 microbiological testing and analytical chemistry laboratory services. Our 14 global laboratory locations are comprised of eight fully integrated labs within Sterigenics' sterilization facilities and 6 stand-alone labs.

Our Wiesbaden, Germany Testing Portfolio

The new lab space provides increased capacity for bioburden testing, BI Sterility, bacterial endotoxin testing (BET), and EO residual analysis. A brand new 100 m² cleanroom with both GMP grade A and B space is already fully operational and offers new tests in product sterility. This expanded lab, with its world-class facilities, will become a hub for future expansion in microbiology services in Europe.

The testing portfolio is based on 2 pillars:

Sterility Assurance

Once a sterilization method has been validated for a particular product and the product is being manufactured, routine sterility testing must be performed to demonstrate the absence of viable microorganisms. These tests include bioburden tests, quarterly dose audits, BI Sterility, BET testing, B/F testing, and many others.

- Bacterial Endotoxins Test
- Biological Indicator – Population Verification
- Biological Indicator – Sterility Testing
- EO Residual Tests
- Product Bioburden – Medical Device
- Radiation Quarterly Audits (QDAs)
- Product Sterility Testing
- Bacteriostasis/Fungistasis Testing

Sterility Validation

With the combined resources and expertise of Nelson Labs and Sterigenics, our understanding of material compatibility, sterilization science, validation approaches, cycle optimization, and analytical chemistry you can count on a reliable and compliant validation strategy.

- Ethylene Oxide Sterilization Validations
- Filter Sterilization Validations
- Product Inoculations
- Sterilization Exposure Cycles
- Sterilization Supplies (BIs & PCDs)
- Sterilization Validation – Radiation

Contact our team of experts today to learn how we can get your product to market

+49 611 880 46 178 | ServiceCenter@nelsonlabs.com

Accreditation ISO 17025

ML-0029 rev1