Medistri

Providing Sterilisation & Laboratory Services for the world's most innovative healthcare companies.

From the Blog

Sterilisation: Understanding Load Variables

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In Sterilisation, the configuration of the load plays a decisive role in ensuring the effectiveness, safety, and consistency of the process. At Medistri, we support our customers by delivering sterilisation solutions that offer controlled flexibility - always in full compliance with industry and international standards. Managing load variables effectively means not only meeting regulatory requirements but also gaining operational efficiency and efficacy throughout the supply chain.

Understanding Load Variables in Sterilisation
Load variables refer to the composition and arrangement of products within the sterilisation environment - whether inside an EO sterilisation chamber or a steam autoclave. These include the quantity of products, their orientation, packaging formats, material types, and the overall density of the load.
Each of these factors plays a critical role in how the sterilising agent - EO gas or saturated steam - circulates, penetrates, and reaches all surfaces of the product. Complex geometries, dense packaging, or absorbent materials can impede uniform exposure, making it essential to evaluate and control these variables to ensure consistent and effective sterilisation outcomes.

Load Configuration Standard Compliance
The configuration of the load directly affects process parameters such as concentration, temperature, humidity, and gas exposure. For that reason, it is a central focus during the validation of any sterilisation process.
At Medistri, each sterilisation cycle is validated using a worst-case load configuration. This involves defining the most challenging setup across a customer's product range - taking into account high absorbency rates, complex pathways, and dense packaging. By validating against the most demanding conditions, Medistri ensures the robustness of every subsequent sterilisation cycle.
Even in situations where industry-standard tools for measuring absorbency are limited, Medistri applies data-driven validation practices to ensure the safety and reproducibility of each load configuration.

Adapted to Real-World Manufacturing Conditions
Manufacturers often need to sterilise different types of products within the same production flow. This may include products with varying formats, packaging styles, or material compositions - all within the same load.
To meet these real-world needs, Medistri's sterilisation systems are designed to manage variation while maintaining control. Our chambers are equipped with advanced monitoring and control systems that ensure uniform temperature distribution and EO gas exposure, even in mixed or variable loads.
This level of control enables our customers to sterilise products efficiently, without needing to compromise on batch planning or production schedules.

Regulatory Considerations for Sterilisation Load Validation
The ANSI/AAMI/ISO 11135-1:2014 standard provides guidance on managing load variability in sterilisation, emphasizing that:

- Load configurations should be validated to ensure that all products receive uniform sterilisation.
- A worst-case reference load should be identified based on material absorbency, density, and structural complexity.
- Penetration and exposure must be verified, particularly for products with complex pathways or high-density materials.

Supporting Flexibility with Scientific Control
Medistri helps manufacturers maintain flexibility without adding risk. Whether supporting small-volume R&D batches or optimising load configurations for high-throughput production, we align the sterilisation process with the specific requirements of your product and packaging.

A Reliable Partner in Sterilisation Process Design
Medistri's integrated approach to sterilisation combines technical expertise with responsive service. By helping customers design their load variation before the sterilisation validation, we help ensure that your sterilisation process remains both compliant and operationally effective - regardless of product complexity or production volume.

Learn more about our Sterilisation expertise by visiting our website here or contact our dedicated team at contact@medistri.com.

— The Medistri Team

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