

# TECHNICAL BRIEF

## ENSURING STERILITY ...

Production consumables are essential in healthcare settings such as pharmaceutical compounding rooms, aseptic manufacturing lines, and biotechnology laboratories. In these environments, sterility is non-negotiable to safeguard the integrity of the final product.

## WHY STERILITY MUST BE PROVEN

Sterility is not a visible characteristic; it must be verified through rigorous processes. Non-sterility cannot be distinguished with the naked eye, as microorganisms like bacteria, viruses, fungi, and spores are too small to detect without specialized tools. For this reason, adherence to Good Manufacturing Practices (cGMP) and validation procedures is essential to ensure truly sterile consumables.

## STANDARDIZED GUIDELINES FOR VALIDATION

The production of validated sterile wipers, whether dry or pre-wetted, required careful adherence to detailed steps outlined by international standards organizations. Entities such as the American National Standards Institute (ANSI), the Association for the Advancement of Medical Instrumentation (AAMI), and the International Organization for Standardization (ISO) provide critical guidance on sterility validation. References such as ANSI/AAMI/ISO Standard 1137 and European Union standards EN 552 and EN 1174 offer best practices for sterilization, treating wipers with the same level of care as medical devices.

## ACHIEVING REQUIRED LEVELS OF STERILITY

Manufacturers are expected to achieve sterility at a probability of 1 part per million, defined as Sterility Assurance Level (SAL) of  $10^{-6}$ . This high standard of sterility is typically accomplished through gamma irradiation, among other validated methods.

## VALIDATION: MORE THAN A SINGLE STEP

When gamma irradiation is a key step in sterilization, it alone does not constitute validation. A validated sterile product requires robust data to confirm that the entire manufacturing process consistently achieves sterility. Validation encompasses both methodical processes and thorough documentation.

## DOCUMENTATION REQUIREMENTS FOR VALIDATION

Manufacturers must provide detailed data to meet the requirements for validated sterile wipers, including:

- Evidence that the radiation dose achieving an SAL of  $10^{-6}$  does not damage the wipers or compromise their performance.
- Bioburden data from production lots collected on a quarterly basis.
- Proof that non-sterile units comply with validation criteria when subjected to the sterilization process.
- Comprehensive dose mapping, including maximum and minimum irradiation levels and configurations for each production lot.
- Packaging integrity data to confirm that sterility is maintained throughout the product's lifecycle.

Only after providing this level of documentation can wipers be marketed as "Validated Sterile Wipers."

## FINAL THOUGHTS

Sterility is a critical component of consumables used in healthcare and manufacturing. Achieving sterility requires more than compliance—it requires validation backed by extensive documentation. By adhering to these rigorous standards, manufacturers can ensure the safety and reliability of their products.

## ABOUT COBEAL

Cobeal specializes in engineering, procurement, construction, installation, and commissioning (EPCIC) for complex environments. Globally recognized for cleanroom expertise, we innovate sustainable solutions that redefine contamination control and air quality standards. With over 60 years of experience, Cobeal combines precision engineering, advanced materials, and cutting-edge technology to meet the challenges of critical sectors, including aerospace, pharmaceuticals, and semiconductors. Our commitment to excellence and environmental stewardship drives groundbreaking advancements, shaping the future of cleanroom and environmental engineering.

***We control the environment so you can control everything else***

