

## Validation Guide

## Ethylene Oxide Biological Validation Process Guideline For Process Challenge Devices (PCDs) (per ISO 11135 and EN 550)

## **EO Half-Cycle Processing**

- 1. Three 1/2 cycles are required for validation.
- 2. Product biological indicators should be placed inside the load at the most difficult place to sterilize.
- 3. Place temperature and humidity sensors as required.
- 4. PCD's should be placed outside the load on the same cartons as containing the product biological indicators.
- 5. Process the 1/2 cycle validation run using minimum pre-conditioning time, the 1/2 cycle EO process parameters and the minimum specified Aeration time.
- 6. Remove all temperature and humidity sensors, biological indicators and the PCD's from the load.
- 7. Send the biological indicators and the PCD's to the Microbiology Laboratory for testing per the Instructions For Use as soon as possible.
- 8. Repeat until three successful(no growth) 1/2 cycles have been processed.

## EO Survival-Cycle Processing

- 9. A cycle of short duration from which biological indicator survivors can be recovered should also be run to document the adequacy of the recovery technique.
- 10. Product biological indicators should be placed inside the load at the most difficult place to sterilize.
- 11. Place temperature and humidity sensors as required.



- 12. PCD's should be placed outside the load on the same cartons as containing the product biological indicators.
- 13. Process the 1/2 cycle validation run using minimum pre-conditioning time and a minimum EO exposure time.
- 14. Remove all biological indicators and the PCD's from the load prior to aeration.
- 15. Send the biological indicators and the PCD's to the Microbiology Laboratory for testing per the Instructions For Use as soon as possible.
- 16. There should be at least one product biological and one PCD survivor from the Survivor cycle. If not, repeat the cycle using a shorter EO exposure time.
- 17. Remove all temperature and humidity sensors from the load after aeration.