

Wipak's Steriking® brand heat-seal and self-seal paper/poly sterilization packaging have been validated for use in ethylene oxide (EO) sterilization by an FDA-registered, ISO 13485 certified independent testing laboratory.

The critical parameters for effective EO sterilization are temperature, time, moisture and EO concentration. An effective EO sterilization pouch must be compatible with the temperature and moisture levels utilized in the EO sterilization process and also must be permeable to both moisture and EO gas to allow for effective delivered lethality inside the pouch. The validation approach for the Steriking® pouches addressed all these issues: It should be noted that the studies were conducted with both the smallest and largest pouch in the "product family" so the data generated was applicable to all Wipak's Steriking® paper/poly pouches.

- A delivered lethality study was conducted with both single and double pouch configurations. Pouches containing biological indicators (BI) and a simulated product were exposed to a 30 minute cycle at 725-735 mg/l EO, 55-60 C and 50 – 80% RH. The study demonstrated that the pouches were compatible with the parameters of the EO cycle and that lethality could be delivered inside the pouches demonstrating both moisture and EO sterilant penetration.
- A shelf-life study was conducted with post EO-exposed pouches. The challenge cycle was a 60 minute cycle at 725-735 mg/l EO, 55-60 C and 50-80 RH. The study validated a 60 month shelf life and demonstrated the maintained integrity of the pouches utilizing both seal-peel and dye penetration testing.

In conclusion, the independent validation testing of Steriking® packaging has demonstrated their compatibility with the EO sterilization process. The challenge cycles used were representative of typical healthcare and industrial cycles and were in fact at the higher end (worst case challenge) of typical cycle parameters. Since the validation studies were conducted with both representatives of the smallest and largest pouches in the family, the data from the studies can be applied to all Steriking® paper/poly packaging sizes.