

**STERIKING®**

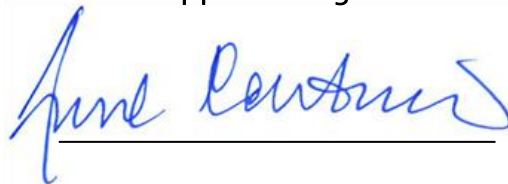
**STERIKING® Tyvek® Pouches and Rolls\***

**TEST REPORT**

**Double Pouching Efficiency**

WIPAK OY  
Wipak Medical  
P.O. Box 45  
15561 Nastola  
Finland

Approved by:



*[Handwritten signature]*

Date: 8.7.2010

\*Steriking is a registered trademark of Wipak. Tyvek is a registered trademark of Du Pont



## 1 INTRODUCTION

This test was designed to evaluate the sterilization efficiency when STERIKING® Tyvek® packages were double packed and sterilized in a VH<sub>2</sub>O<sub>2</sub> cycle.

The purpose of the study was to demonstrate that the VH<sub>2</sub>O<sub>2</sub> process is capable to eliminate a population of 10<sup>6</sup> CFU *Bacillus stearothermophilus* spores in case of double packed STERIKING® Tyvek® packages are subjected to the VH<sub>2</sub>O<sub>2</sub> sterilization process. Acceptance was based on negative BIs.

## 2 EQUIPMENT AND MATERIALS

- 2.1 Sterilizer unit: STERRAD® 100S, serial number 016309, at Central Hospital of Päijät-Häme, Keskussairaalankatu 7, FIN-15850 Lahti
- 2.2 Biological indicators: STERRAD® CycleSure® 24 (REF 14324), LOT 32291Z (EXP 2011-03)
- 2.3 Incubator
- 2.4 STERIKING® Tyvek® packages: REF LTS7520 – LOT 0802, REF LTS1025 – LOT 0706, REF LTS1530 – LOT 0603, REF LTSS1 – LOT 0802, REF LTSS4 – LOT 0902, REF LTSS5 – LOT 0606

## 3 TEST PERFORMANCE

- 3.1 BI vials were placed internally to a LTS or LTSS pouch which was closed either by sealing it with a heat sealer (LTS references) or with tape included (LTSS references). Then these (inner) packages were placed into other (outer) ones which were closed accordingly.
- 3.2 Three identical sterilization cycles were performed in Sterrad 100S.
- 3.3 Packages were opened and BIs were collected and transferred to the incubator with the reference BI (unprocessed). All the vials were incubated and monitored for 48 hours at 58°C.

## 4 TEST RESULTS

- 4.1 After sterilization all LTS and LTSS test packages were intact and their process indicators had changed color appropriately from yellow to blue. The chemical indicators on top of the CYCLESURE® 24 BI vials had changed from red to golden yellow.
- 4.2 After incubation time processed BIs showed negative growth and the unprocessed reference BI showed positive growth.

## 5 CONCLUSION

The data generated in this study demonstrates that the STERIKING® Tyvek® packages can be used as a double pack concept when such circumstances are required. They enable the sterilizing agent to penetrate into the inner package and eliminate the spores of *Bacillus stearothermophilus*. STERIKING® Tyvek® products in a double pack concept have shown their compatibility for use when exposed to VH<sub>2</sub>O<sub>2</sub> sterilization.