



## STERIKING® Seal Control Sheet

As per new ISO 11607:2:2006 there should be a documented process validation program demonstrating the efficacy and reproducibility of all sterilization and packaging processes. Sterile barrier system manufacturing process including the sealing of preformed sterile barrier systems shall be validated. The validation shall include at a minimum, an installation qualification, an operational qualification and a performance qualification at this order. Operational qualification (OQ) in sealing process is to obtain and document evidence that the sealer operates within predetermined limits when used in according with its operational procedures.

The critical sealing parameters are temperature, time and pressure. These parameters have to be adjusted as per the packaging material sealed.

### Intended Use

STERIKING® Seal Control is designed for operational qualification of sealing process. In sealing process the following quality properties\* of the seal shall be controlled:

- intact seal for a specified seal width
- channels and open seals
- punctures or tears
- material delamination or separation

These properties can be controlled with STERIKING® Seal Control.

### Technical Data

The STERIKING® Seal control is constructed of medical grade paper (70 g/m<sup>2</sup>) and a multiply PET/PP-plastic laminate (12/40 microns).

### Performance Characteristics

1. Set the temperature of the sealer to 165 – 190°C (329 – 374°F).
2. Make a test seal on the laminate-paper area of the SEAL CONTROL sheet
  - The green colour of the laminate is turning to darker green under the sealing area. The factory made side seals of the Seal control sheet are reference of intact, acceptable seal.
3. Check the test seal quality
  - Check that the sealing lines are continuous darker green, having no white areas which mean that the seal is not intact.
  - If there are white areas in otherwise continuous green sealing area the sealing parameters and the functionality of the sealer should be checked and adjusted. Check the sealing temperature, time and pressure and make the adjustments needed. If it does not help take the sealer to maintenance.
  - After the corrective actions the test should be repeated until the acceptable result is achieved.
4. Fill in, sign and file the Seal Control

### Storage Recommendations & Shelf Life

It is recommended that the STERIKING® products are kept in the original, closed transport carton and are stored in dry and clean conditions protected from direct sunlight and excessive moisture.

The shelf life is event-related and not time -related. It is recommended that the products are put to their end use within 10 years of manufacture. The recommended "Best before" date and the manufacturing date are stated on the carton label. Each sheet bears a code number enabling traceability of the production history. The code is YYMM (year / month) e.g. 0701 = January 2007 etc.

### Sales and Transport Packing

Sheets are packed in corrugated cardboard cases 250 sheets per case. The cases are packed then into a transport carton, 4 cases per carton.

### Steriking® SC - Seal Control Sheet

Code	Sheets/case
SC250	250
SC250	4 x 250 (1000)

