

Product Specification

Form Ref. ST-69240 Rev.: A Date: 31 December 2008



STERIKING® Paper Bags

The STERIKING® Paper bags are manufactured for use as sterilization packages in steam sterilization processes in health care establishments. The common time/temperature combinations are 3 minutes at 134°C or 15 minutes at 121°C.

Conformity to International Standards

The STERIKING® Paper bags conform to the following product standards: ISO 11607-1:2006, ISO 11607-2:2006 and EN 868-4:1999.

The products are registered under Class 1 as accessories in compliance with the European Medical Device Directive MDD/93/42 which is incorporated in the Finnish Act 1505/94 and its statutes.

To show compliance with MDD/93/42 the CE mark is printed on the label of the transport carton.

STERIKING® sterilization packages are designed, validated, and manufactured to suit their intended purposes

Technical Data & Performance Characteristics

The STERIKING® Paper bags are manufactured from EN 868-3:1999 compliant bleached medical grade paper (60 g/m²) printed with necessary printing and an indicator for steam sterilization. The opening of the bag is coated with the heat sealable glue. Raw materials are FDA approved. Recommended sealing temperature for final closing is approximately 180° C (376° F).

Product Specific Features

Tensile strength

Minimum strength: 2,2 kN/m

Opening

The opening line is marked for guidance.

Lot Coding

Each bag bears a code number enabling traceability of the production history.

Chemical Indicator

conform to ISO 11140-1:2005 class 1: Process indicators.

Steam indicator changes color from pink to brown

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 its end use within 5 years of manufacture. The recommended "Best before" –date is stated on the carton label.

Sales and Transport Packing

The STERIKING® Paper bags are packed in recyclable, brown hard carton cases. As an inner cover against moist and dust the bags are wrapped in a recyclable plastic cover.

Please refer to the local/national regulations regarding waste disposal.

Labelling: Each case bears a label with the necessary information/instructions of the contents in accordance with EN 868-4:1999.

In Case of Complaint

In event of any complaint, the lot number and identification code must be provided by the complainant. For evaluation of claimed product, a defective sample (or a digital photo) and description of the defect together with an unused specimen must be made available to Wipak.

STERIKING® is a registered trademark of Wipak Medical





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Steriking® Paper Bags

Product Code	Size (mm)	Packing Unit
PB1	90 X 50 X 125	1000
PB2	110 X 30 X 190	1000
PB3	125 X 50 X 250	1000
PB4	140 X 75 X 250	500
PB5	140 X 50 X 330	500
PB6	165 X 50 X 380	500
PB7	180 X 95 X 380	500
PB8	190 X 65 X 330	500
PB9	250 X100 X 380	500
PB10	300 X 75 X 530	250 *)
PB12	380 X125 X 610	250 *)

All the bags are manufactured with a double folded bottom, but PB10 and PB12 (*) are with a single folded bottom.

This specification refers to the named product group and shall be valid until the next revision. Other product related documents may be available upon request.

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