

Product Specification

Form Ref. ST-69300 Rev.: A2 Date: 11 February 2011



STERIKING® AC Strips

The STERIKING® indicator strips are manufactured in accordance with Good Manufacturing Practice Regulations promulgated by Food and Drug Administration (FDA) in USA for use as a monitoring indicator of the sterilization process carried out for the items requiring sterilization, such as surgical instruments and dressings in hospitals.

The STERIKING® indicator strips for steam sterilization are designed to monitor the attainment of the critical variables for the sterilization processes. The STERIKING® AC strips are class 4 multi-variable indicators and intended to indicate exposure to steam sterilization cycle at 134°C for 3.5 minutes or at 121°C for 15 minutes.

Conformity to International Standards

The STERIKING® AC Strips are manufactured under ISO 9001:2000 and ISO 13485:2003 certification and are in accordance with the following norms: ISO 11140-1:2005 (Class 4, multivariable indicators).

STERIKING® monitoring products are designed, validated, and manufactured to suit their intended purposes.

Technical Data & Performance Characteristics

STERIKING® multi-variable indicator strips are manufactured from bleached carton printed with both ordinary ink and indicator ink. The AC250/500 strip is 20 cm long and perforated so it can be split into two 10 cm strips. After exposure to the specified processing conditions they provide a clear color change which remains unchanged and as such is suitable for use as a permanent record. The multivariable indicator strips are printed with a reference color to show the endpoint reaction from white to black.

Storage Recommendation & Shelf Life

No special precautions need to be taken in respect of storage or transportation of STERIKING® indicator strips. However, they should not be exposed to very high humidity or to direct sunlight. It is recommended to keep them in their original packing until the moment of use.

If stored according to the instructions the shelf life of STERIKING® AC strips is at least four years from the date of manufacture.

Sales and Transport Packing

STERIKING® indicator strips are packed in recyclable, brown hard carton cases (5000 strips each), consisting smaller units of 250 strips each carton box.

Labelling: Each case bears a label with the necessary information/instructions of the content in accordance with ISO 11140-1:2005.

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.

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Steriking® AC Strips

Code	Strips/case
AC250/500	4x250, 20x250

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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