

Envase

100 o 250 tiras en hojas de 10 unidades.

Datos en el envase: código y descripción del producto, proceso para el cual se utiliza, presentación, clasificación según la normativa e información en la etiqueta.

Peso por caja: 37,7 g (100 u) o 73,4 g (250 u)

Etiquetado

En el envase: lote y fecha de vencimiento.

Posibles mercados de destino

Área de la Salud, Industria Alimenticia, Farmacéutica y de Productos Médicos.

Otra información relevante (opcional)

Antes de su utilización se recomienda leer las instrucciones operativas del producto.

Nota: si es necesario, se deberán especificar límites para los parámetros de cada producto.

Descripción de los peligros conocidos y/o previsibles y de situaciones que podrían representar un peligro para el producto.

No almacenar el producto cerca de agentes esterilizantes.

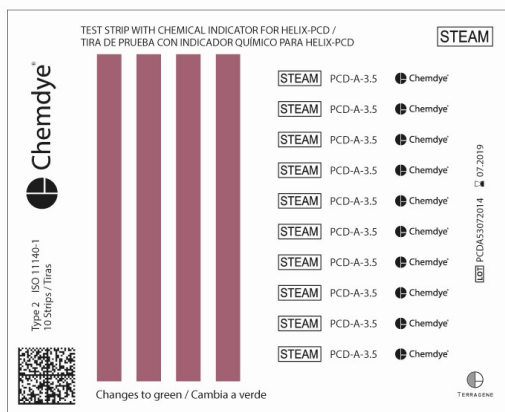
No esterilizar por OE, Calor Seco, Formaldehído u otro proceso de esterilización diferente al Vapor.

No volver a utilizar el esterilizador hasta que el cambio de color del indicador sea el indicado en el producto.

PCD-A-3.5

Chemical Indicator for use in Helix-PCD system

For Steam sterilization processes control.



Usage

Designed to be used in the Helix-PCD system for secure load release.

Conditions: 3.5 minutes, 134 °C.

Applicable regulation

ISO 11140-1:2014

Product Classification

Class 1, according to risk.

Authorization

Designed under Quality management Systems standards ISO 9001:2008 and ISO 13485:2012. ANMAT (Argentinean National Administration of Drugs, Food and Medical Technology) PM-1614-4.

Characteristics

Type 2 Chemical Indicator.

Self-adhesive strip printed with indicator ink. Size: 77 x 6 mm.

10 strips per sheet. Size: 80 x 100 mm.

Initial color: **purple**

Final color: **green**

NOTE: If the 4 bars change to the final color, the sterilization cycle was successful, the load can be securely released. If one or more bars did not turn to the final color, this shows a failure in sterilizing agent penetration, the load cannot be considered sterile, that is, it cannot be released.

100 % Toxic Heavy Metals free



Environmental conditions during manufacture

15-30 °C (room temperature), RH 30-80 %.

Storage conditions

T = 10-30 °C, RH 30-80 %, keep out of direct light.

Transportation conditions

Storage conditions should be strictly followed. Transport in closed and reinforced boxes in order to avoid damages. Transportation of this product does not represent a risk for health.

Shelf-life

5 years

Packing

100 or 250 strips in sheets of 10 units.

Packing information: product code and description, process in which is used, presentation, classification according to regulation and data on label.

Weight per box: 37,7 g (100 u) or 73,4 g (250 u)

Labelling

On product's box: batch number and expiration date.

Possible target markets

Healthcare, Food, Pharmaceutical and Medical industries.

Other important information (optional)

Read product's directions for use thoroughly before use.

Note: When necessary, limits for each product's parameters should be specified.

Description of identified and/or predictable risks which could represent a risk for the product

Do not store the product near sterilizing agents.

Do not expose this product to EO, Dry Heat, Formaldehyde or any sterilization process other than Steam.

Do not reuse the sterilizer until the color change of the chemical indicator is the one indicated in the product.