

KH2X15-3.5BD/P

Helix-PCD + Bowie & Dick simulation test strips Kit

For monitoring vacuum-assisted steam sterilizers.



Usage

Designed to assess air removal and steam penetration in large and small vacuum-assisted steam sterilizers.

Condition: Bowie & Dick cycle: 3.5 minutes, 134 °C.

Applicable regulation

Designed under Quality Management System standards ISO 13485:2016/NS-EN ISO 13485:2016.

EN 867-5, EN 285, ISO 11140-1, ISO 11140-4

Classification

Class 1, according to risk (ANMAT).

Characteristics

Helix-PCD

Plastic capsule of great resistance and durability, to hold a Chemical Indicator designed for this system. The capsule is connected to a high resistance plastic tube of 1.5 m length (see catalogue for other lengths) and 2 mm internal diameter. Special silicone connector coated by external connector.

PCD-A-3.5BD

Type 2 Chemical Indicator.

Self-adhesive strip printed with indicator ink. Size: 76 x 6 mm.

10 strips per sheet. Size: 80 x 98.5 mm.

Initial color: **blue**

Final color: **dark grey/black**

Authorization: ANMAT (Argentinean National Administration of Drugs, Food and Medical Devices) PM-1614-4.

NOTE: If 4 bars change to the final color, the result is successful, the sterilizer works properly. If one or more bars have not turned to the final color, this shows a failure in sterilizing agent penetration, therefore an equipment malfunction.

100 % Toxic Heavy Metals free



Environmental conditions during manufacture

T = 15-30 °C, RH 30-80 %.

Storage conditions

T = 10-30 °C, RH 30-80 %, store in dark place.

Transport conditions

Storage conditions should be strictly followed.

Transport in closed and strengthened boxes in order to avoid damages. The transport of this product does not represent a risk for health.

Shelf life

PCD-A-3.5BD: 5 years.

Helix-PCD: 250 cycles.

Packing

250 PCD-A-3.5BD strips in sheets of 10 units + 1 Helix-PCD + 1 cotton bag.

Packing information: manufacturer information, storage conditions and data on label.

Labelling

On product's packing: product code and description, process for intended use, presentation, classification according to regulation, kit batch number and CDPCD batch number, manufacture date, expiration date, bar code and datamatrix code.

On helix-PCD bag: product code and description, presentation, batch number, bar code and datamatrix code.

On PCD-A-3.5BD packing: product code, process for intended use, presentation, color change, batch number, manufacture date, expiration date, bar code and datamatrix code.

Possible target markets

Healthcare, Food, Pharmaceutical and Medical industries.

Other important information

Read product's instructions for use thoroughly before use.

Precautions

Do not store the product near sterilizing agents.

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

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