

Infection Control Division | **Chemical Indicators**

## BD125X/2 Chemical Indicator Bowie-Dick Test Pack



### Usage

Bowie-Dick test pack detects inadequate air removal and steam penetration in vacuum-assisted Steam sterilizers. Cycles of 16.9 min at 121 °C, 4 minutes at 132 °C and 3.5 minutes at 134 °C.

### Applicable regulation

Designed under Quality Management System standards ISO 13485:2016/NS-EN, ISO 13485:2016, ISO 11140-1:2014 and ISO 11140-4:2007.

### Authorization

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

### Classification

Class 1, according to risk (ANMAT).

### Characteristics

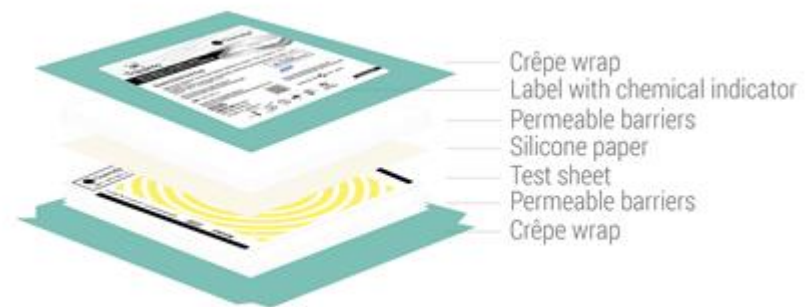
Type 2 Chemical Indicator.

Initial Color: **yellow**.

Final Color: **dark brown/black** (should change homogeneously in the whole sheet).

Size: 16 mm x 125 mm x 125 mm (approximate).

Assembly: permeable barriers - 1 silicone paper - 1 test sheet - permeable barriers. Wrapped with crepe paper.



NOTE: Air removal or steam quality problems will be shown as heterogeneous color change into dark brown/black on the test sheet, such as lighter areas in the center or a non-uniform color change.

100 % Lead Free



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To interpret results visually, use the reference guide found in the Indications for Use. Optionally, the readout of the chemical indicator can be done using Trazanto Automatic Quality Control and Traceability System (see instructions for use in device's manual).

### Environmental conditions during manufacture

T = 15-30 °C, RH = 30-80 %.

### Storage conditions

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

### Transport conditions

It is recommended to store it away from sunlight and at a temperature between 10 - 30 °C.

Products should be transported in closed and reinforced boxes in order to avoid damages.

The transport of this product does not represent any risk for human health.

Acceptable excursions during transport are as follows:

T = 2-10 °C and T = 30-37 °C for no longer than seven days. No restrictions for relative humidity.

### Shelf life

5 years.

### Packing

20 units per box.

Packing information: description code, process for intended use, classification according to regulation, storage conditions, manufacturer information and data on label.

### Labelling

On product's packing: chemical indicator (type 1) line, printed with steam reactive ink, turns from blue (not exposed) to dark grey/black (exposed). Product code and description, intended use, process for intended use, classification according to regulation, storage conditions, batch number, expiration date, manufacture date and datamatrix code.

On product's packing: Product code and description, process for intended use, color change, presentation, batch number, expiration and manufacture 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.

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### Precautions

Do not store the product near sterilizing agents.

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

Do not use a Bowie-Dick Test Pack in gravity displacement steam sterilization cycles (where there is no pre-vacuum phase to check) or any kind of sterilization processes other than vacuum-assisted.

Do not reuse the sterilizer until the chemical indicator has changed homogeneously into the color indicated in the product.