

# CD22

## Chemical Indicator

*For monitoring Steam sterilization processes*



### Usage

Control of Steam sterilization processes. **Conditions:** 121 °C, 10 minutes // 134 °C, 2 minutes.

### Applicable Regulation

ISO 11140-1:2014

### Product Classification

Class 1, according to risk.

### Authorization

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

### Characteristics

Type 1 Chemical Indicator.

One-side-laminated strips printed with indicator ink.

Size: 105 x 18 mm

Initial color: **blue**

Final color: **black**

### 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**

250 or 500 strips per box.

Packing information: product description, product presentation, operating instructions, manufacturer information and data on label.

Weight per box: 107,5 g (250u.)

**Labelling**

Only on product's box: product code and description, process for intended use, operating instructions, classification according to regulation, 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 or any sterilization processes other than Steam.

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