

# CD16

## Multi-variable Chemical Indicator

*For monitoring Ethylene Oxide sterilization processes*



### Usage

Control of Ethylene Oxide (EO) sterilization processes. **Conditions:** 600 mg/l EO, RH 60%, 30 °C, 30 minutes // 600 mg/l EO, RH 60%, 54 °C, 20 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 4 Multi-variable Chemical Indicator.

Double punched card strips printed with indicator ink.

Size: 200 x 15 mm

Initial color: **Purple/brown**

Final color: **Green**

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**

250 strips per box.

Packing information: product code and description, process for intended use, operating instructions, product presentation, classification according to regulation, batch number, manufacturer information and expiration date.

**Labelling**

Information only on product's box.

**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 Steam, Dry Heat or any sterilization processes other than EO.

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