

Infection Control Division | **Chemical Indicators**

## IT26-1YS Unique Point Chemical Integrator For Steam sterilization processes

### Usage

Control of Steam sterilization processes between 121 °C and 135 °C.

### Applicable regulation

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

### Authorization

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

### Classification

Class 1, according to risk (ANMAT).

### FDA 510(k)

K191021.

### Characteristics

Type 5 Integrating Indicator (according to ISO 11140-1).

One-side-laminated strips printed with indicator ink.

Size: 70 mm x 23 mm.

Initial color: **yellow**.

Final color: **black**.

100 % Toxic Heavy Metal free.



Integration condition calibrated with the kill time of a  $10^6$  *Geobacillus stearothermophilus* ATCC®\* 7953 population, calculated in BIER (Biological Indicator Evaluator Resistometer). Conditions: saturated steam at 121 °C, 128 °C, 135 °C.

The product ensures an adequate control of the efficacy of sterilization processes (temperature, time, quality of steam).

To interpret results visually, use the reference found in the indicator. 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).

\*ATCC® is a registered trademark of American Type Culture Collection.

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## IT26-1YS Unique Point Chemical Integrator

### For Steam sterilization processes

**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 respect the storage conditions during transport.

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.

**Shelf life**

5 years.

**Packing**

200 or 500 units per aluminum foil bag.

Packing information: product description, instructions for use, regulation, storage conditions, manufacturer information and data on label.

**Labelling**

On product's packing: product code and description, process for intended use, classification according to regulation, color change, presentation, batch number, 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 or any sterilization processes other than Steam.

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



División Control de Infecciones | **Indicadores Químicos**

## IT26-1YS Integrador Químico de Un Punto

### Para procesos de esterilización por Vapor

#### Uso previsto

Control de procesos de esterilización por Vapor entre 121 °C y 135 °C.

#### Normativa aplicable

Diseñado bajo normas de Sistema de Gestión de Calidad ISO 13485:2016/NS-EN, ISO 13485:2016. ISO 11140-1:2014.

#### Habilitación

ANMAT PM 1614-4.

#### Clasificación

Clase 1, de acuerdo al riesgo (ANMAT).

#### FDA 510(k)

K191021.

#### Características

Indicador Integrador Tipo 5 (conforme ISO 11140-1).

Tira unilaminada impresa con tinta indicadora.

Tamaño: 70 mm x 23 mm (aproximado).

Color inicial: **amarillo**.

Color final: **negro**.

**100 % Libre de Metales Pesados Tóxicos.**



La condición de integración está calibrada con el tiempo de muerte de una población de  $10^6$  esporas de *Geobacillus stearothermophilus* ATCC® 7953, calculada en un BIER (Biological Indicator Evaluator Resistometer).

Condiciones: Vapor saturado a 121 °C, 128 °C, 135 °C.

El producto asegura un control adecuado de la eficacia del proceso de esterilización (temperatura, tiempo, calidad del vapor).

Para interpretación de los resultados en forma visual, utilice la referencia que se encuentra en el indicador.

Opcionalmente, la lectura del indicador químico puede realizarse empleando el Sistema Automático de Control de Calidad y Trazabilidad Trazanto (ver instrucciones en el manual del dispositivo).

#### Condiciones ambientales de producción

T= 15-30 °C, HR 30-80 %.

#### Condiciones de almacenamiento

T= 10-30 °C, HR 30-80 %, mantener al abrigo de la luz.



