

CD240

Multi-variable Chemical Tubes

For Dry Heat sterilization control



Usage

Control of Dry Heat sterilization processes.

Conditions: for Dry Heat conveyor ovens working at 180 °C, 12 minutes. BLUE SPOT.

Applicable Regulation

EN ISO 11140-1:2009

Product Classification

Class 1, according to risk.

Authorization

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

Characteristics

- Class 4 Multi-variable Chemical Indicator (contained in the ampoule).
- Glass ampoule. 7 mm external diameter. Wall of 0.7 – 0.8 mm thick. Length of 40 mm. Marked at one end for identification.
- Ampoule volume: 0.25 ml
- Initial color: **red**
- Final color: **green**

NOTE: Sterilization proceeds, the liquid changes color from red to GREEN. If after treatment, the liquid remains red or amber the materials should be re-sterilized and a fresh tube must be used. A color guide in the instruction provides an instant visual check of the results.

Environmental conditions during manufacture

15-30 °C (room temperature), RH 30-80 %.

Storage conditions

Store at 2-20 °C, preferably in refrigerator, RH 35-60%. Avoid freezing.

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

2 years

Packing

100 tubes per box.

Packing information: product description, operating instructions, classification according to regulation, manufacturer information and data on box's label.

Weight per box: 108, 7g.

Labelling

Only on product's box: product code and description, product presentation, operating instructions, process for intended use, 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, Steam or any sterilization processes other than Dry Heat.

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