

Product Technical Data Sheet

Form No.: FTP-055 Rev.: E

Product Name: SteriTec Emu-Graph

Emulator

Product Type: Chemical Emulator

Reorder Number: CI 131

Description: The SteriTec Emu-Graph emulator provides an integrated response to steam sterilization in prevacuum sterilizers operating at 132-135°C for 3 minutes or longer. The Emu-Graph gives a visible confirmation of the attainment of sterilization conditions at the location within the sterilizer chamber.

Performance Characteristics:

The Emu-Graph has two different indicator inks printed on each indicator. The user can determine:

- 1. If neither indicator bars turn green, the emulator has been subjected to insufficient steam sterilization conditions.
- 2. If the 2 MIN bar turns green, biological kill was achieved, but not with a sufficient safety margin.
- 3. If the both bars turn green, a sufficient safety margin was obtained.

Color Change: Purple to Green.

Critical Parameters: (in a hospital steam prevacuum sterilizer)

| Indicator | Time at 132°C | Time at 134°C | Time at 135°C |
|-----------|---------------|---------------|---------------|
| 2 MIN | 2 minutes | 1.5 minutes | 1 minutes |
| 4 Min | 4 minutes | 3.5 minutes | 3 minutes |

Stated Values: (as determined in a steam resistometer)

| Indicator | Time at 132°C | Time at 134°C | Time at 135°C | |
|-----------|---------------|---------------|---------------|--|
| 2 MIN | 3 minutes | 2 minutes | 2.25 minutes | |
| 4 Min | 4.5 minutes | 4 minutes | 3.75minutes | |

Indicator Stability: Before and After Sterilization = Excellent

Physical Characteristics:

Lamination: Top and Bottom **Dimensions:** 3" L X .75" W

Indicator Substrate Material: Print Blotter

Quantity / Bag: 250 Bags / Case: 20 Selling Unit: Case

Environmental Limitations:

Storage: 32° - 104°F (0° - 40°C) at 10-90% humidity when stored in the re-sealable bag provided.

Shelf Life: 3 years from date of manufacture

FDA 510(k) Release to Market Date: None. Not for release in USA.

Standards Classifications:

ISO 11140-1:2005, Class 6

ITEM: SteriTec Emu-Graph Emulator, CI 131

PRODUCT TECHNICAL DATA SHEET, FTP-131

Change History

| CO Number | Rev | Change Description | Date Released |
|--------------|-----|---|------------------|
| | | | |
| 1569 | D | Updated critical parameters and stated values. Updated standards. | 08/04/2008 |