



## Product Technical Data Sheet

Form No.: FTP-236 Rev.: A

**Product Name:** SteriTec Heli-Check Hollow Load Process Challenge Device

**Product Type:** Process Challenge Device

**SteriTec Reorder Number:** LT 104

**Customer Name:** SteriTec

**Customer Catalog No.:** LT 104

**Description:** The Heli-Check Hollow Load PCD was designed to verify air removal, deep vacuum achievement, steam penetration levels, and exposure levels necessary for lumen sterilization conditions pre-vacuum steam sterilizers. It can be utilized in each sterilization load, as an independent control device for decisions regarding load release or for daily release of pre-vacuum steam sterilizers should hollow load test be required.

### Performance Characteristics:

The Heli-Check PCD is a reusable device with an emulator chemical indicator strips that are placed inside the device for each sterilization load. The indicator strip will change color when exposed steam sterilization conditions and can be used as a permanent record by removing the back release liner and sticking the indicator to a sterilization record.

**Color Change:** Purple to Green

**Critical Parameters:** (in a standard steam pre-vacuum sterilizer)  
3.5 minutes at 134°C

**Stated Values:** (as determined in a steam resistometer)  
None required for Class 2 special tests.

**Indicator Stability:** The indicator color change is stable after exposure to steam sterilization conditions and will not revert back to the original.

### Physical Characteristics:

**Dimensions:** 3" X .219"

**Substrate Material:** Bio Index paper with adhesive and release liner on back side.

**Units / Bag:** 250

**Bags/Case:** 6

**Selling Unit:** Case

### Environmental Limitations:

**Storage:** 32° - 104°F (0° - 40°C) at 10-60% humidity when stored in the re-sealable bag provided.

**Shelf Life:** 3 years from date of manufacture.

**SteriTec FDA 510(k) Release to Market Date:** None. Product not sold in the USA.

### Standards Classifications:

ISO 11140-1: 2005, Class 2

EN 867-5

**ITEM:** SteriTec Heli-Check Hollow Load Process Challenge Device, LT 104

**PRODUCT TECHNICAL DATA SHEET, FTP-236**

**Change History**

<b>CO Number</b>	<b>Rev</b>	<b>Change Description</b>	<b>Date Released</b>
1507	A	New Product, Initial Release.	04/24/2008