Product Technical Data Sheet

Form No.: FTP-137 Rev.:A **Product Name:** Green Card Bowie-Dick Test Card – Starter Kit

Product Type: Bowie-Dick Indicator Kit

SteriTec Reorder No.: BD 116

Description: The SteriTec Green Card – Starter Kit consists of one box of Green Card Bowie-Dick Test Cards and one Test Card Holder. The SteriTec Green Card Bowie-DickTest Cards are designed as an environmentally safe lead free method for daily monitoring of pre-vacuum steam sterilizers to detect air leaks, inadequate steam penetration and vacuum pump failures. The Green Card is designed to simulate a large towel pack as defined by AAMI ST46 and meets the AAMI ST66 and EN 867-3 test methods for detecting temperature drops and the presence of air. The card is placed in a Test Card Holder, the holder is then placed in the sterilizer in the most difficult to sterilize area. A sterilization cycle for 3.5 minutes at 132° C is run.

Performance Characteristics:

If no appreciable air is present in the sterilizer chamber after vacuums are drawn, the steam will penetrate to the middle of the test card and turn the indicator sheet a uniform green color. If a small amount of air is present, sufficient to cause a 2° C temperature drop in the middle of an AAMI ST46 bowie-dick towel pack, the air will migrate to the middle leaving the center of the card a purplish color rather than uniform green.

Color Change: Indicator Card – Purple to Green for complete change and no air leak **Complete Color Change Time:** 3.5 minutes at 132° C with no air leaks **Indicator Stability:** Before and After Exposure = Excellent

Physical Characteristics:

Dimensions: Indicator Card: 3.5" X 1.8" Test Card Holder: 3.75" X 5.5" X 1.25" Material: Indicator Card: EXLP Blotter Paper Test Card Holder: Anodized Aluminum Color: Test Card Holder: Green Quantity / Box: 31 tests and 1 Holder Boxes / Case: 8 Selling Unit: Case

Environmental Limitations: Storage: 50° - 100° F (10° – 38° C) at 10 - 60% humidity

Shelf Life: 3 years from date of manufacture

FDA 510(k) Release to Market Date: August 11, 2003, K024293

Standards Classifications:

AAMI ST60, Class 2 EN 867-1, Class B ISO 11140-1, Class 2 AAMI ST66 EN 867-3