

## **Certificate of Quality**

**Product Name:** NLA - ^ST^ 100/CS TSB II 5ML **Lot Number:** 805461 **Product Number:** R9021555 **Expiration Date:** 2011-02-03

(YYYY-MM-DD)

This product has been manufactured, processed and packaged in accordance with Quality Systems Regulation, 21 CFR Part 820. Representative samples were tested per Remel Quality Control specifications and were found to meet performance criteria for this product.

**Steris Part Number: PC100153** 

Organism ChallengeATCCPerformance CriteriaGeobacillus stearothermophilus7953Growth, yellow color change

Challenge organism was incubated up to seven days at 55-60C; inoculum is <100 CFU

## **Absorbance Results:**

Wavelength/Standard Concentration Color Absorbancy Range Result 558 nm/14 mcg Standard 0.432-0.554 Pass 558 nm/22 mcg Standard 1.200-1.584 Pass

Product has been tested and is certified to demonstrate an absorbancy between the 14 mcg and the 22 mcg standard.

## **Microbial Load Evaluation:**

This product has been terminally steam processed and validated to deliver a SAL of 10 (-6). Product has been statistically sampled and incubated at temperatures of 55-60C and 30-35C. Samples were acceptable for microbial content and aesthetic value following 7 days incubation at the stated temperatures.

## **Physical Characteristics:**

Appearance: Red to Red Orange, Clear Broth

pH: 7.3 +/- 0.2

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Certificate results were obtained at time of release. End users are encouraged to assure product meets internal standards at time of use.

Signed

Quality Assurance Supervisor