

BIOLOGICAL INDICATOR CERTIFICATE OF ANALYSIS

Reorder no. NSS-E6/2x10
Organism: *Bacillus atrophaeus* ATCC #9372
Lot:
Expires: YYYY-MM-DD
Population¹: x 10⁶ per carrier strip

EO Gas Performance Data⁴

D-value ² min.	Survives ³ min.	Killed ³ min.

Dry Heat Performance Data

Temperature	D-value ² min.	Survives ³ min.	Killed ³ min.
160 ± 2.0°C			

Dry Heat Z-value²: °C

- ¹ After a preliminary heat treatment of 80-85°C for 10 min.
² Determined at the time of manufacture using fraction negative procedures in an AAMI/ISO compliant test vessel.
³ Calculated using USP, AAMI, and ISO survival and kill time formulas.
⁴ Determined at 54 ± 1.0°C, 60 ± 10% relative humidity, 600 ± 30mg/L 100% EO.

The D-value(s) are reproducible only when exposed and cultured under the exact conditions used to obtain results and reported above. The user would not necessarily obtain the same results; therefore, should determine the suitability for their particular use.

Purity: Shall not contain any contamination that would adversely affect the performance or the stability characteristics of the biological indicator.

This document certifies that the biological indicators are produced for supplier in compliance with the manufacturer's Quality Assurance specifications and suggested performance parameters published in the current United States Pharmacopeia (USP), and comply to AAMI / ISO 11138-1:2017 guidelines and all appropriate subsections.

Certified by: _____
Quality Assurance Manufacturer's Representative

Complete Quality Control testing results are available upon request with supplier.

Exposure:

Record the sterilizer number, load number and processing date in your record processing note book. Place the NSS BI inside a test pack of similar design to items being sterilized or area within the package deemed as the most difficult area to achieve sterilization. Test the most challenging area in the sterilizer as indicated in the sterilizer's instruction manual (e.g. the middle of the sterilizer chamber). Use a sufficient number of NSS BI's throughout the load, a minimum of ten (10) is recommended. Process the load according to the sterilizer manufacturer's instructions. Remove the NSS BI and aseptically transfer to appropriate microbiological culture medium.

Activation:

Transfer each spore strip into a tube containing soybean casein digest broth. The tubes should be placed in the incubator immediately after the strips are cultured. Their placement in an optimized growth environment is necessary to gain accurate results.

Incubation:

Incubate at 30°C - 40°C for seven days, regularly checking for spore growth (visual color change or turbidity). Results should be read no later than seven days after incubation.

Test Results and Interpretation:

The media should be observed for growth for no less than seven days. No visual turbidity and/or color change in the media indicates proper sterilization conditions were achieved. Record negative (no growth) results after full incubation according to your standard operating procedures. The appearance of a visual pH color change and/or turbidity indicates bacterial growth (positive). Any positive result should be reported immediately to a supervisor and the sterilizer taken out of service until resolved. Always retest the sterilizer with additional NSS BI's within the test load. NSS BI's can be sub-cultured to verify organism when desired.

Use of Controls:

As a control, an unprocessed NSS BI (from the same lot) should be prepared for incubation preferably for each cycle tested. The positive control shall become turbid and/or has a color change within the seven days of incubation. When the control becomes positive, it should be recorded and then autoclaved and discarded according to the instructions for use. Positive controls are intended to ensure that viable spores are present on the NSS BI and the incubator performs properly, they are not intended to be used for comparing test results. Incubation of positive controls should be read no later than seven days.

Storage:

Storage: Room Temperature (15°C – 30°C). Keep away from high temperature, humidity and sterilants. Do not use after expiration date.

Disposal:

Autoclave, steam at 121°C for not less than 30 minutes, or incinerate (standard microbial waste: non-pathogenic species).

Technical Datasheet:

Reference the technical datasheet for more detailed information.