ETIGAM

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BIOLOGICAL INDICATOR CERTIFICATE OF ANALYSIS

Reorder no.	NSS-E#
Organism:	*Bacillus atrophaeus* ATCC #9372
Lot:	####
Expires:	YYYY, MM DD
Population[1]:	## x 10^6 per carrier strip

EO Gas Performance Data[4]

D-value[2]	Survives[3]	Killed[3]
## min.	## min.	## min.

Dry Heat Performance Data

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

Dry Heat Z-value[2]: ##°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 is reproducible only under the exact conditions under which it was determined. The user may not obtain the same result and therefore should determine the suitability of the biological indicator for its particular use.

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.

INSTRUCTIONS FOR USE

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 37 ± 2°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:
Store at controlled room temperature as defined by USP. USP-controlled room temperature is thermostatically controlled to 20-25°C (68-77°F) while allowing for excursions between 15-30°C (56-86°F). Reference the USP for the complete definition. Protect from light, chemicals and sterilants (e.g. ethylene oxide), excessive heat and moisture. Optimal humidity range for long term storage is 20 to 70%. Do not desiccate.

Disposal:
To reduce the possibility of contaminating your test area, it is recommended that all positive cultures be autoclaved at 121°C for not less than 30 minutes. Any indicators on hand after the expiration date should be handled in the same manner.

Technical Datasheet:
Reference the technical datasheet for more detailed information.