Cat. No. DS-100; DS-100-Red **Quantity 100 Strips**
Cat. No. DS-500; DS-500-Red **Quantity 500 Strips**
Cat. No. DS-1000; DS-1000-Red **Quantity 1000 Strips**

BIOLOGICAL INDICATOR CERTIFICATE OF PERFORMANCE

Organism: *Bacillus atrophaeus* ATCC 9372
Population[1]: 2.2×10^6
Organism: *Geobacillus stearothermophilus* ATCC 7953
Population[1]: 2.0×10^5
Lot: D67
Expires: 2020-12-31 (YYYY-MM-DD)

Determined Performance Data

Process	Temperature	D value[2]	Survives	Killed
Ethylene Oxide	Below[3]	2.9 min.	12.6 min.	29.9 min.
Dry Heat	160 ± 2°C	1.6 min.	7.0 min.	16.5 min.
Saturated Steam	121.1 ± 0.5°C	1.7 min.	5.7 min	15.8 min
Saturated Steam	132.2 ± 0.5°C	5 sec	17 sec.	46 sec.
Chemical Vapor	132.0°C Unsat. Chem. Vapor[4]	0.96 min.	--------	--------

[1]Determined after preliminary heat treatments. *Bacillus atrophaeus* at 80-85°C for 10 minutes. *Geobacillus stearothermophilus* at 95-100°C for 15 minutes.
[2]Determined at the time of manufacture using fraction negative procedures.
[3]54 ± 1°C (130°F), 600 ± 30 mg/L EO, 60 ± 10% RH
[4]Vapo-Steril solution
*Calculated using USP,AAMI and ISO survival and kill time formulas

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 the user is responsible for determining the suitability for their particular use.

This document certifies that these biological indicators meet our Quality Assurance specifications, SPSmedical specification no. 001, and current manufacturing requirements of the United States Food and Drug Administration. These indicators are certified to meet, up to the expiration date, the stated survival, kill, and population specifications. Test apparatus used to determine the resistance characteristics are in compliance with current USP and AAMI specifications.

Kristin Crandall

Quality Assurance Approval
January 17, 2019

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USE OF BIOLOGICAL STERILITY INDICATORS

These biological indicators consist of *Geobacillus stearothermophilus* and *Bacillus atrophaeus* spores inoculated into chromatography paper strips (1 1/2 x 9/32 inches). *Geobacillus stearothermophilus* is used to test steam and chemical vapor sterilizers. *Bacillus atrophaeus* is used to test dry heat and ethylene oxide sterilizers. The indicators should be used as described below. Alternative methods should be validated by the user.

The indicators should be placed in areas of the pack or load most inaccessible to steam, chemical vapor, ethylene oxide or dry heat sterilant. For example, indicators should be placed in the lower geometrical center, and the upper and lower regions of both front and rear of the load to be sterilized. A standard procedure should be established for the routine evaluation of each sterilizer. When the sterilization cycle is complete, remove the indicators from the test load(s) and deliver them to the laboratory for testing.

STERILITY TESTING TECHNIQUE

All sterility tests must be performed using rigid aseptic technique.

The indicators should be transferred to sterile casein soy digest media within 4 hours of the end of the sterilization cycle. Aseptically open the glassine envelope and use sterile forceps or tweezers to remove the strip from the envelope. Aseptically place the strip into the media tube, identify the tube, and place in the appropriate incubator. Incubate steam or chemical vapor tests at 58-62°C (*Geobacillus stearothermophilus*) and incubate dry heat or ethylene oxide tests at 35-39°C (*Bacillus atrophaeus*).

Incubate for seven days. Observe the tubes periodically. The development of growth is indicative of failure of the sterilization process. Typical *Bacillus atrophaeus* growth consists of an orange (or infrequently, cream colored) pellicle on the surface of the growth media. Typical *G. stearothermophilus* growth consists of a white sediment on the bottom of the culture media tube.

CONTROLS

One or more positive controls (indicators not exposed to the sterilization process) should be incubated with the exposed indicators to verify that the culture media possesses suitable growth promoting properties and that unexposed indicators contain viable spores. Lack of growth in the positive control indicates that the media fails to support growth and/or the indicators are non-viable.

A negative control consisting of one or more tubes of culture medium should be included in each test series. Absence of growth in the negative control would verify that the test medium was properly sterilized.

STORAGE

Store at controlled room temperature as defined by the United States Pharmacopeia*. Controlled room temperature is thermostatically controlled between 20 and 25°C, with a mean kinetic temperature of not more than 25°C, with excursions to 15°C to 30°C allowed. *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.

OTHER RECOMMENDATIONS

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 before discarding. Any indicators on hand after the expiration date should be handled in the same manner or incinerated.