



STERIS Corporation Biological Operations
SPECIAL ORDER CUSTOM CERTIFICATE OF PERFORMANCE

CATALOG NUMBER: NA501-34A

PRODUCT NAME: Spordi Strip

PRODUCT LOT NUMBER: G20016

B.I. LOT NUMBER: 0700

EXPIRATION DATE: September 10, 2021

MANUFACTURE DATE: April 15, 2020

***Geobacillus stearothermophilus* 7953:**

Mean Population Recovery* (CFU): **1.8 x 10⁵**

Survival Time (Min.): **5.6**

D₁₂₁ Value** (Min.***): **1.7**

Kill Time (Min.): **15.7**

Incubate at 55° to 60°C for 7 days

***Bacillus atrophaeus* NRRL B4418:**

Mean Population Recovery* (CFU): **3.3 x 10⁶**

Survival Time (Min.): **N/A**

D_{1.0} Value** (Min.***): **N/A**

Kill Time (Min.): **N/A**

D_{DH} Value** (Min.***): **1.8**

Survival Time (Min.): **8.2**

Kill Time (Min.): **18.9**

Incubate at 30° to 35°C for 7 days

* Colony forming units determined after a preliminary heat treatment.

** Saturated Steam, 121±0.5°C or 600±30mg/L EO using 100% EO, 54±1°C, 60±10% RH or 160±1°C Dry Heat

*** Determined at time of manufacture by fraction negative procedure after graded exposure to sterilization conditions.

Store at 2° to 24°C and between 30% to 80% RH. **DO NOT** use after the indicated **expiration date**.

Dispose of as you would any other microbiological waste (121°C for a minimum of 30 minutes).

This certifies that the product listed above has been tested in compliance with current versions of ISO 11138-1 and ISO 11138-2.

**NOTE: Special order -
Use and Suitability are the customer's responsibility.**

Quality Systems Representative: *Linda Munnings* Date: *4/28/2020*

Reviewed By: *Maggie Sillander* Date: *4/20/2020*

LIMITATION OF LIABILITY AND INDEMNITY

Nothing in this Certificate of Performance shall, or is intended to, alter, expand, or diminish the terms and conditions of sale governing your purchase of the Biological Indicator Product from STERIS. In no event, whether as a result of breach of warranty, or tort (including negligence and strict liability) shall STERIS or its suppliers be liable as a result of any statement or information contained in this Certificate of Performance. In addition, STERIS shall not be liable for any consequential or incidental damages including, without limitation, loss of use or damage to your products or equipment, cost of substitute products, or down time costs, allegedly caused by the Biological Indicators Products. The responsibility of STERIS for damages due to injuries or death caused by the Biological Indicator Product shall be limited to that portion of such damages as might be attributable to the negligence or strict liability or other tortious conduct of STERIS.

PC600035 Revision Level: AW PR# 09590
EFFECTIVITY DATE: 4/17/2019