
We solve problems with confidence and creativity.

Monitoring Products for Dry Heat

Steam-Formaldehyde

Chlorine Dioxide
NAMSA’s Sterilization Products Division manufactures and markets a wide range of high quality Sterilization Monitoring Products used globally. Our domestic and international market segments include pharmaceutical, medical device, contract sterilizers, laboratories, healthcare, dental, food and beverage, and biotech companies. NAMSA is a proud manufacturer and distributor of a full line of Sterilization Monitoring Products including:

- Biological Indicators
- Chemical Process Indicators
- Chemical Indicating Inks
- Custom Indicator Labels
- Quality Control Test Suspensions
- Spore Suspensions
- Culture Media
- Incubators

Our products are tailored to suit many different sterilization processes including:

- Steam
- Irradiation
- Vaporized Hydrogen Peroxide/Plasma
- Ethylene Oxide
- Dry Heat
- Formaldehyde
- Chlorine Dioxide

NAMSA’s sterilization products are manufactured in an FDA regulated facility certified to ISO 13485:2003. Globally NAMSA maintains a comprehensive list of accreditations and certifications. Please visit www.NAMSA.com to learn more.

Visit our webpage at www.NAMSA.com/Products
Call us at 419-662-4345 (outside the U.S.) and 800-860-1888 (toll-free)
Fax us at 419-666-1715
Email us at productorders@namsa.com

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Inoculated Carriers & Biological Indicators

NAMSA manufactures a comprehensive line of Inoculated Carriers and Biological Indicators (BIs) for use in monitoring Dry Heat sterilization processes. Our most popular inoculated carriers and biological indicators are manufactured using state of the art equipment, which provides assurance that each glassine pouch contains a biological indicator consistent in population, purity and dimension.

- Convenient shelf packages of 100 units per box
- Room temperature storage conditions (15°C to 30°C), relative humidity of 30% to 80% is recommended
- Products are accompanied by a Certificate of Analysis and are certified with population, purity, and resistance characteristics (D-value, z-value, survival and kill where applicable)

Biological Indicator – ISO 11138-4 Compliant

NAMSA manufactures a biological indicator for Dry Heat sterilization which is compliant with ISO 11138-4. The BI consists of a 6 mm x 30 mm filter paper inoculated with *Bacillus atrophaeus* spores, packaged in a glassine envelope, which is then wrapped in foil and placed into a paper sleeve. The configuration offers an increased D-value at 160°C of not less than 2.5 minutes meeting the requirements for dry heat resistance as outlined in ISO 11138-4.

- Place BIs into the most difficult area of the sterilizer or device/article to be sterilized.
- In general, a minimum of 10 BIs are utilized in each cycle.
- Compliant with ISO 11138-4

**Biological Indicator – ISO 11138-4 Compliant**

*Bacillus atrophaeus* Cell Line 9372
24 month shelf-life

<table>
<thead>
<tr>
<th>NAMSA Code</th>
<th>Packaging</th>
<th>Population</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>STN-06DH</td>
<td>Glassine/Foil/Paper Sleeve</td>
<td>10⁶</td>
<td>100/box</td>
</tr>
</tbody>
</table>

**Traditional Spore Strips**

Consist of inoculated filter paper, each 6 mm x 30 mm, individually packaged in easy-to-handle glassine pouches.

- The strips can be easily removed from the glassine pouch by tearing or peeling the pouch open for transfer to culture media or challenge device assembly
- Compliant with ISO 11138-1

**Mini Spore Strips**

Consist of inoculated filter paper, each 2 mm x 10 mm, packaged in a variety of options. The small size of the Mini Spore Strips allows them to fit into areas of a device where standard sized spore strips cannot be used, such as within a syringe barrel, inside tubing or under a cap.

- NAMSA Mini Spore Strips are available packaged in glassine envelopes of two sizes: a larger envelope 25 mm x 50 mm (STN-062) or a mini glassine envelope 25 mm x 25 mm (STN-062MG)
- The product is also available as an inoculated carrier in bulk (no glassine packaging)(STN-062B)
- Population levels other other than 10⁶ are available upon request
- Compliant with ISO 11138-1

**Traditional Spore Strips**

*Bacillus atrophaeus* Cell Line 9372
24 month shelf-life

<table>
<thead>
<tr>
<th>NAMSA Code</th>
<th>Population</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>STN-04</td>
<td>10⁴</td>
<td>100/box</td>
</tr>
<tr>
<td>STN-05</td>
<td>10⁵</td>
<td>100/box</td>
</tr>
<tr>
<td>STN-06</td>
<td>10⁶</td>
<td>100/box</td>
</tr>
</tbody>
</table>

**Mini Spore Strips**

*Bacillus atrophaeus* Cell Line 9372
24 month shelf-life

<table>
<thead>
<tr>
<th>NAMSA Code</th>
<th>Packaging</th>
<th>Population</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>STN-062</td>
<td>Glassine envelopes</td>
<td>10⁶</td>
<td>100/box</td>
</tr>
<tr>
<td>STN-062B</td>
<td>Bulk</td>
<td>10⁶</td>
<td>100/box</td>
</tr>
<tr>
<td>STN-062MG</td>
<td>Mini-glassine envelopes</td>
<td>10⁶</td>
<td>100/box</td>
</tr>
</tbody>
</table>
Biological Indicators for Dry Heat

Spore Discs
NAMSA Spore Discs are available in two different sizes, 3 mm and 6 mm diameters. The discs are designed to be utilized as an inoculated carrier for placement directly into areas of a device which are the most difficult to sterilize.

- Ideal for use in tubing, lumens and other devices/instruments where larger BIs and carriers cannot be utilized
- NAMSA’s manufacturing process is designed to ensure that the entire length of the threads contains a consistent number of spores
- Compliant with ISO 11138-1

<table>
<thead>
<tr>
<th>NAMSA Code</th>
<th>Disc Diameter</th>
<th>Packaging</th>
<th>Population</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>THN-06</td>
<td>3 mm</td>
<td>Bulk</td>
<td>$10^6$</td>
<td>100/box</td>
</tr>
<tr>
<td>DN18-06</td>
<td>3 mm</td>
<td>Bulk</td>
<td>$10^6$</td>
<td>100/box</td>
</tr>
</tbody>
</table>

Spore Threads

- Ideal for use in tubing, lumens and other devices/instruments where larger BIs and carriers cannot be utilized
- NAMSA’s manufacturing process is designed to ensure that the entire length of the threads contains a consistent number of spores
- Compliant with ISO 11138-1

<table>
<thead>
<tr>
<th>NAMSA Code</th>
<th>Description</th>
<th>Packaging</th>
<th>Population</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>THN-06</td>
<td>Cotton Thread 25 mm x 0.1 mm</td>
<td>Bulk</td>
<td>$10^6$</td>
<td>100/box</td>
</tr>
</tbody>
</table>

Spore Suspensions
NAMSA manufactures Spore Suspensions utilized in Dry Heat sterilization processes. The Spore Suspensions are pure suspensions of spores with known resistance characteristics and a variety of population levels standardized per 0.1 mL. The Spore Suspensions allow for direct inoculation of products, typically to verify sterility of devices where a traditional biological indicator spore strip cannot be used. They can also be used for a variety of other microbiological tests including cleaning effectiveness studies, Bioburden percent recovery and Bacteriostasis/Fungistasis (BF) testing.

- Pharmaceutical grade glass vials with screw cap and septum
- Convenient vials of 10 mL volumes suspended in Water for Injection (WFI)
- Spore Suspensions require storage under refrigerated conditions (2°C to 8°C)
- Each vial of Spore Suspension is accompanied by a Certificate of Analysis detailing the source, assayed population, resistance characteristics on paper carrier and expiration date
- ISO 11138-1 compliant

<table>
<thead>
<tr>
<th>NAMSA Code</th>
<th>Population per 0.1 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUN-02</td>
<td>$10^2$</td>
</tr>
<tr>
<td>SUN-03</td>
<td>$10^3$</td>
</tr>
<tr>
<td>SUN-04</td>
<td>$10^4$</td>
</tr>
<tr>
<td>SUN-05</td>
<td>$10^5$</td>
</tr>
<tr>
<td>SUN-06</td>
<td>$10^6$</td>
</tr>
<tr>
<td>SUN-07</td>
<td>$10^7$</td>
</tr>
<tr>
<td>SUN-08</td>
<td>$10^8$</td>
</tr>
</tbody>
</table>
Chemical Process Indicators

NAMSA Dry Heat Chemical Process Indicators (CPIs) are manufactured with NAMSA’s Eco Friendly Indicating Inks. The CPIs meet the requirements of NAMSA’s Quality System (ISO 13485) and have been validated per standard cycles outlined in ISO and USP for Depyrogenation processes. Our Chemical Process Indicators provide a fast and consistent visual check on items that were exposed to Dry Heat processes.

- Consistent and irreversible color transition
- No light sensitivity issues
- Permanent pressure-sensitive adhesive
- 24 month shelf-life
- Room temperature (15°C to 30°C) storage
- Each shipment is accompanied by a Certificate of Conformance to ensure product quality and consistency

### Chemical Process Indicators

<table>
<thead>
<tr>
<th>NAMSA Code</th>
<th>Description</th>
<th>Indicators Per Roll</th>
<th>Unexposed</th>
<th>Exposed</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPI-DH01</td>
<td>Plain 12.7 mm Dots (Dry Heat) Orange to Brown (≤ 180°C)</td>
<td>1,000</td>
<td><img src="image" alt="Unexposed: Orange" /></td>
<td><img src="image" alt="Exposed: Brown" /></td>
</tr>
<tr>
<td>CPI-DP1</td>
<td>Plain 12.7 mm Dots (Depyrogenation) High temperature or Depyrogenation - Pink to Violet/Dark Brown (≤ 250°C)</td>
<td>500</td>
<td><img src="image" alt="Unexposed: Pink" /></td>
<td><img src="image" alt="Exposed: Brown" /></td>
</tr>
</tbody>
</table>

Chemical Indicator Strip

NAMSA’s Dry Heat Chemical Indicator Strip is manufactured with NAMSA’s Eco Friendly Indicating Ink technology. This new innovative indicator strip demonstrates exceptional performance and is customized for the most widely utilized Dry Heat processes. NAMSA evaluates the performance of every lot to ensure consistent and reliable performance.

- Lead & latex free
- Irreversible color transition from Orange to Brown
- Class 4 exposures at 160°C for 40 minutes
- Room temperature storage (15°C to 30°C)
- Each shipment includes a Certificate of Conformance for assurance of product quality and performance
- ISO 11140-1 Class 4 Compliant

### Chemical Indicator Strips

<table>
<thead>
<tr>
<th>NAMSA Code</th>
<th>Description</th>
<th>Dimensions</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>DH-250</td>
<td>Chemical Indicator Strip – Class 4</td>
<td>115 mm x 19 mm</td>
<td>250/box</td>
</tr>
</tbody>
</table>

Ask us about NAMSA’s custom sterilization indicator program.
Colors shown are representations of printed ink initial and signal colors but may vary from actual use.
Biological & Chemical Indicators for Steam-Formaldehyde

Biological Indicators - Traditional Spore Strips
NAMSA manufactures Biological Indicators (BIs) for use in monitoring Steam-Formaldehyde sterilization processes. Our BIs are manufactured using precise care, which provides assurance that each glassine pouch contains a biological indicator consistent in population and purity.

• Consist of inoculated filter paper, each 6 mm x 30 mm, individually packaged in easy-to-handle glassine pouches
• The strips can be easily removed from the glassine pouch by tearing open for transfer to culture media
• Convenient shelf packages of 100 units per box
• Room temperature storage conditions (15°C to 30°C)
• Products are accompanied by a Certificate of Analysis
• Compliant with ISO 11138-1

Traditional Spore Strips
Geobacillus stearothermophilus Cell Line 7953
24 month shelf-life

<table>
<thead>
<tr>
<th>NAMSA Code</th>
<th>Population</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>STSF-05</td>
<td>10⁶</td>
<td>100/box</td>
</tr>
<tr>
<td>STSF-06</td>
<td>10⁶</td>
<td>100/box</td>
</tr>
</tbody>
</table>

Chemical Process Indicators
NAMSA Steam-Formaldehyde Chemical Process Indicators (CPIs) are manufactured with NAMSA’s Eco Friendly Indicating Inks and meet performance specifications as outlined in ISO 11140-1 Sterilization of health care products - Chemical indicators - Part 1: General requirements, for Class 1 Process Indicators. Our CPIs provide a fast and consistent visual check on items that were sterilized by Steam Formaldehyde.

• Consistent and irreversible color transition from Violet to Green
• No light sensitivity issues
• Permanent pressure-sensitive adhesive
• 24 month shelf-life
• Room temperature storage (15°C to 30°C)
• Each shipment is accompanied by a Certificate of Conformance to ensure product quality and consistency

Chemical Process Indicators
24 month shelf-life

<table>
<thead>
<tr>
<th>NAMSA Code</th>
<th>Description</th>
<th>Indicators Per Roll</th>
<th>Unexposed</th>
<th>Exposed</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPI-SF01</td>
<td>Plain 12.7 mm Dots</td>
<td>5,000</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Chemical Indicator Strip
NAMSA’s Steam-Formaldehyde Chemical Indicator Strip is manufactured with NAMSA’s Eco Friendly Indicating Ink technology, permanent pressure-sensitive adhesive and tear resistant medical grade Tyvek®. Convenient design allows for use as an indicator strip or remove the backing before or after exposure to use as a label. This new innovative indicator strip demonstrates exceptional performance and is customized for the most widely utilized Steam-Formaldehyde processes. Performance of every lot is evaluated to ensure consistent and reliable performance.

• Lead & latex free
• Irreversible color transition from Violet to Green
• Class 4 exposures at 70°C for 15 minutes using 1 mol/L Formaldehyde
• Room temperature storage (15°C to 30°C)
• Each shipment includes a Certificate of Conformance for assurance of product quality and performance
• ISO 11140-1 Class 4 Compliant

Chemical Indicator Strip
24 month shelf-life

<table>
<thead>
<tr>
<th>NAMSA Code</th>
<th>Description</th>
<th>Dimensions</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>SFVG-250</td>
<td>Chemical Indicator Strip –</td>
<td>76 mm x 19 mm</td>
<td>250/box</td>
</tr>
<tr>
<td></td>
<td>Class 4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Ask us about NAMSA’s custom sterilization indicator program. Colors shown are representations of printed ink initial and signal colors but may vary from actual use.
Biological Indicators - Traditional Spore Strips

NAMSA manufactures Biological Indicators (BIs) for use in monitoring Chlorine Dioxide sterilization processes. Our BIs are manufactured using precise care, which provides assurance that each pouch contains a biological indicator consistent in population and purity.

- Consist of inoculated filter paper, each 6 mm x 30 mm, individually packaged in easy-to-handle Tyvek®/Tyvek® pouches.
- The strips can be easily removed from the pouch for transfer to culture media
- Convenient shelf packages of 100 units per box
- Room temperature storage conditions (15°C to 30°C)
- Products are accompanied by a Certificate of Analysis and are certified with population and purity
- Compliant with ISO 11138-1

Prepared Culture Media

NAMSA’s Prepared Culture Media consists of an exclusively formulated Tryptic Soy Broth (TSB) modified with pH indicator. Our Prepared Culture Media is available for use with both Bacillus atrophaeus (GMBTB-100) and Geobacillus stearothermophilus (GMBCP-100). A reduced incubation time for Dry Heat, Steam-Formaldehyde and Chlorine Dioxide processes has been validated when NAMSA’s prepared Culture Media is used in conjunction with our Biological Indicators.

- Reduced Incubation Times:
  - 48-hour reduced incubation time for Dry Heat when used with Bacillus atrophaeus (GMBTB-100)
  - Please inquire about reduced incubation time for Steam-Formaldehyde when used with Geobacillus stearothermophilus (GMBCP-100)
  - 36-hour reduced incubation time for Chlorine Dioxide when used with Geobacillus stearothermophilus (GMBCP-100)
- Visually distinct results:
  - Purple media transitions to Yellow when positive for Geobacillus stearothermophilus growth
  - Blue/Green media transitions to Yellow when positive for Bacillus atrophaeus growth
- 16 mm x 100 mm flat bottom tubes of Type I borosilicate glass with screw caps
- Each lot is accompanied by a Certificate of Analysis and is certified with growth promotion capabilities using Geobacillus stearothermophilus Cell Line 7953 or Bacillus atrophaeus Cell Line 9372