STERILIZATION MONITORING PRODUCTS

NAMSA™

Known for their consistent, reliable performance, NAMSA sterilization monitoring products are used by pharmaceutical and medical device manufacturers, contract sterilizers, and other related industries.

These products are used to:

- Validate the effectiveness of the sterilization process
- Monitor and assure adequate sterilization of products and instruments
- Monitor every load
- Distinguish processed from unprocessed goods

All NAMSA products require only minimal user training, are manufactured in ISO 13485 certified facilities and meet domestic and international standards.

For additional product information:

Call us at 800-860-1888 (toll-free) or

419-662-4345 (outside the U.S.)

Please visit us at www.namsa.com

E-mail us at productorders@namsa.com

In addition to our line of sterilization monitoring products, NAMSA offers a comprehensive range of testing and consulting services designed to help manufacturers market safe products that meet regulatory compliance standards worldwide. Specific capabilities include materials characterization, function and performance studies, biocompatibility, clinical research services, and sterility assurance.

All NAMSA laboratories are fully certified and accredited according to the highest industry standards.

NAMSA

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Self-Contained Biological Indicators (SCBI)

NAMSA offers Self-Contained Biological Indicators (SCBI) for monitoring steam sterilization processes in spore population levels of 10^5 and 10^6 and for Ethylene Oxide (EO) and Hydrogen Peroxide processes in a 10^6 population. Each SCBI unit consists of a plastic vial with a cap, a crushable glass ampoule with recovery media, and a disc inoculated with spores. SCBIs are ideal for use in monitoring sterilization processes in place of traditional Biological Indicator strips, however there is no need for aseptic transfer of the BI to culture media and SCBIs offer a shortened incubation period.

The recovery medium consists of a modified Soybean Casein Digest Broth with pH indicator. Activate for incubation by depressing the cap completely and crushing the ampoule. Growth is evident by either turbidity and/or a color shift of the media. SCBIs are labeled with the shorter shelf life of the two components; the inoculated disc and ampoule which have independent expiration periods. Store under room temperature (15°C - 30°C) conditions. SCBIs are offered in boxes of 50 units. Each box is accompanied by a Certificate of Analysis and Instructions for Use. NAMSA SCBIs are compliant with ANSI/AAMI/ISO/EN 11138-1 and USP where applicable.

Self-Contained Biological Indicators

NAMSA Code	Sterilization Process	Organism	Pop.	Min. Incubation Period
SCS-05	Steam	*Geobacillus stearothermophilus*	10^5	24 hours
SCS-06	Steam	*Geobacillus stearothermophilus*	10^6	24 hours
SCE-06	EO	*Bacillus atrophaeus*	10^6	48 hours
SCH-06	Hydrogen Peroxide	*Geobacillus stearothermophilus*	10^6	48 hours

NAMSA offers aluminum dry-block incubators for use in conjunction with the SCBIs and spore ampoules. They offer an ambient to 60° C temperature range with a tolerance of ±2° C. The incubator has a removable, clear poly-carbonate 12-well rack allowing for full viewing of all units at a glance.

Incubators

Catalog Number	Description
I-G35-13	Incubator, 120 Volt, 35° C For use in the USA
I-G55-13	Incubator, 120 Volt, 55° C For use in the USA
I-120-35-13	Incubator, 120 Volt, 35° C For use outside the USA
I-120-55-13	Incubator, 120 Volt, 55° C For use outside the USA
I-240-35-13	Incubator, 240 Volt, 35° C
I-240-55-13	Incubator, 240 Volt, 55° C

BIOLOGICAL INDICATORS

Spore Strips

NAMSA offers a full line of spore strips for use in monitoring sterilization processes. Spore strips consist of inoculated filter paper, 6 mm x 30 mm, packaged in glassine peel pouches or envelopes. The glassine packaging provides protection from environmental contaminants during transport post exposure. The spore 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. Spore strips are available in populations from 10^2 to 10^8 for each organism. A lead time may apply for population levels not outlined in the tables below.

Our most popular spore strips are manufactured using state of the art equipment, which provides assurance that each glassine pouch contains a BI consistent in population, purity and dimension. Spore strips are packaged in shelf packs of 100 and labeled with a 15 to 24 month shelf-life based on the organism. Store strips under room temperature conditions (15 - 30° C). Each pack is accompanied by a certificate of analysis. Spore strips are certified for population, purity, and resistance (D-value, Z-value, survival and kill where applicable). NAMSA Biological Indicator strips are compliant with ANSI/AAMI/ISO/ EN 11138 series of standards and USP where applicable.

Ethylene Oxide

Bacillus atrophaeus 24 month shelf-life

NAMSA Code	Spore Population Per Strip
STN - 04	10^4 (10,000)
STN - 05	10^5 (100,000)
STN - 06	10^6 (1,000,000)

Steam

Geobacillus stearothermophilus 24 month shelf-life

NAMSA Code	Spore Population Per Strip
STS - 04	10^4 (10,000)
STS - 05	10^5 (100,000)
STS - 06	10^6 (1,000,000)

Bacillis subtilis 15 month shelf-life

NAMSA Code	Spore Population Per Strip
BS52306	10^6 (1,000,000)

Radiation

Bacillus pumilus 24 month shelf-life

NAMSA Code	Spore Population Per Strip
STP - 06	10^6 (1,000,000)
STP - 07	10^7 (10,000,000)
STP - 08	10^8 (100,000,000)

Combination Strips

Geobacillus stearothermophilus and *Bacillus atrophaeus* 24 month shelf-life

NAMSA Code	Spore Population Per Strip
STNS - 65	10^5 (100,000) *Geobacillus stearothermophilus* 10^6 (1,000,000) *Bacillus atropheaus*

Dry Heat

Bacillus atrophaeus 24 month shelf-life

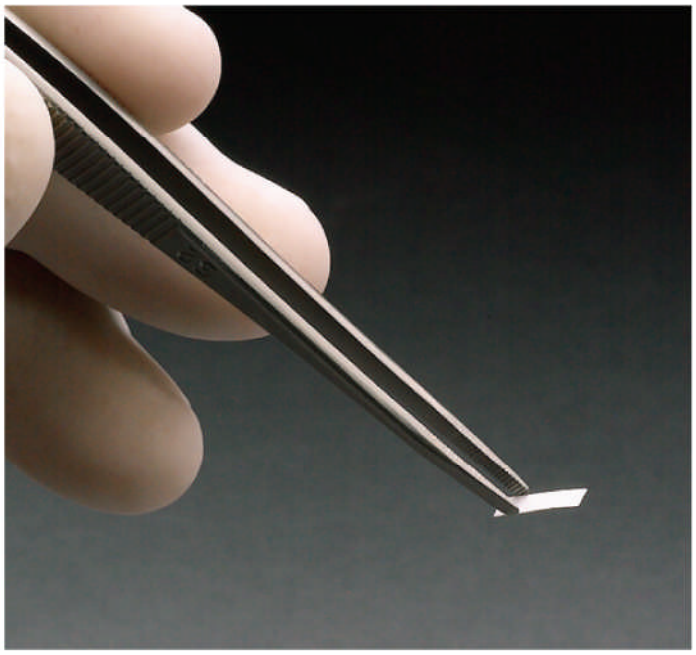
NAMSA Code	Spore Population Per Strip
STN - 06DH	10^6 (1,000,000)

Mini Spore Strips

Mini Spore Strips (2 mm x 10 mm) will fit into small areas of a device where a standard-sized (6 mm x 30 mm) spore strip cannot be used, such as within a syringe barrel, inside tubing or under a cap. Mini spore strips are packaged in shelf packs of 100 strips.

These products are labeled with a 24 month shelf-life from the date of manufacture. Store strips under room temperature conditions (15 - 30° C). Each pack is accompanied by a certificate of analysis. Spore strips are certified for population, purity, and resistance (D-value, Z-value, survival and kill where applicable). NAMSA mini strips are compliant with ANSI/AAMI/ISO/EN 11138 series of standards and USP where applicable.

For availability and lead times of population levels other than 10^6, please inquire.



Mini Spore Strips - Ethylene Oxide or Dry Heat

Bacillus atrophaeus 24 month shelf-life

NAMSA Code	Packaging	Spore Population / Strip
STN - 062	glassine envelopes	10^6 (1,000,000)
STN - 062B	bulk	10^6 (1,000,000)
STN - 062MG	mini-glassine envelopes	10^6 (1,000,000)

Mini Spore Strips - Steam

Geobacillus stearothermophilus 24 month shelf-life

NAMSA Code	Packaging	Spore Population / Strip
STS - 062	glassine envelopes	10^6 (1,000,000)
STS - 062B	bulk	10^6 (1,000,000)
STS - 062MG	mini-glassine envelopes	10^6 (1,000,000)

Custom Biological Indicators

NAMSA can manufacture custom Biological Indicators using a variety of carriers in combination with any organism. Please inquire to obtain additional information about NAMSA's capabilities to manufacture a custom indicator to meet your needs.

Spore Threads - Ethylene Oxide or Dry Heat

Bacillus atrophaeus 24 month shelf life

NAMSA Code	Length	Carrier Type	Spore Population Per Strip	Packaging
THN-06	25 mm	Cotton thread	10^6 (1,000,000)	Bulk

Spore Threads - Steam

Geobacillus stearothermophilus 12 month shelf life

NAMSA Code	Length	Carrier Type	Spore Population Per Strip	Packaging
THS-05	25 mm	Cotton thread	10^5 (100,000)	Bulk
THS-06	25 mm	Cotton thread	10^6 (1,000,000)	Bulk

Spore Wires - Ethylene Oxide

Bacillus atrophaeus 12 month shelf life

NAMSA Code	Length	Carrier Type	Spore Population Per Strip	Packaging
SWN-06	40 mm	Braided steel	10^6 (1,000,000)	Bulk

Spore Wires - Steam

Geobacillus stearothermophilus 12 month shelf life

NAMSA Code	Length	Carrier Type	Spore Population Per Strip	Packaging
SWS-06	40 mm	Braided steel	10^6 (1,000,000)	Bulk

Spore Wires - Hydrogen Peroxide

Geobacillus stearothermophilus 12 month shelf life

NAMSA Code	Length	Carrier Type	Spore Population Per Strip	Packaging
SWH-06	40 mm	Braided steel	10^6 (1,000,000)	Bulk

Spore Coupons - Hydrogen Peroxide

Bacillus atrophaeus 12 month shelf life

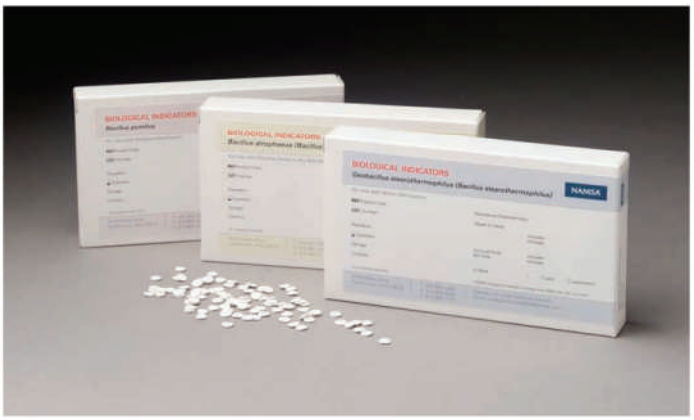
NAMSA Code	Length	Carrier Type	Spore Population Per Strip	Packaging
CPN-06	34 x 7 x 0.9 mm	Steel	10^6 (1,000,000)	Tyvek/Mylar

Spore Coupons - Hydrogen Peroxide

Geobacillus stearothermophilus

CPS-06	34 x 7 x 0.9 mm	Steel	10^6 (1,000,000)	Tyvek/Mylar

Spore Discs



Spore Discs (3 mm and 6 mm diameters) will fit into small areas of a device where a standard-sized (6 mm x 30 mm) spore strip cannot be used, such as within a syringe barrel, inside tubing or under a cap. Spore discs are packaged in shelf packs of 100 discs.

These products are labeled with a 12 to 24 month shelf-life from the date of manufacture. Store discs under room temperature conditions (15 - 30° C). Each pack is accompanied by a certificate of analysis. Spore discs are certified for population, purity, and resistance (D-value, Z-value, survival and kill where applicable). NAMSA spore discs are compliant with ANSI/AAMI/ISO/EN 11138 series of standards and USP where applicable.

For availability and lead times of other population levels or for alternative packaging, please inquire.

Spore Discs - Ethylene Oxide or Dry Heat
Bacillus atrophaeus 24 month shelf-life

NAMSA Code	Disc Diameter	Carrier Type	Spore Population / Disc	Packaging
DN - 06	6 mm	Filter paper	10^6 (1,000,000)	bulk
DN18 - 06	3 mm	Filter paper	10^6 (1,000,000)	bulk

Spore Discs - Steam
Geobacillus stearothermophilus 24 month shelf-life

NAMSA Code	Disc Diameter	Carrier Type	Spore Population / Disc	Packaging
DS - 06	6 mm	Filter paper	10^6 (1,000,000)	bulk
DS18 - 06	3 mm	Filter paper	10^6 (1,000,000)	bulk

Spore Discs - Hydrogen Peroxide
Bacillus atrophaeus 12 month shelf-life

NAMSA Code	Disc Diameter	Carrier Type	Spore Population / Disc	Packaging
GFN-06	9 mm	Glass fiber	10^6 (1,000,000)	Bulk
GFTN-04	9 mm	Glass fiber	10^4 (10,000)	Tyvek/Mylar
GFTN-05	9 mm	Glass fiber	10^5 (100,000)	Tyvek/Mylar
GFTN-06	9 mm	Glass fiber	10^6 (1,000,000)	Tyvek/Mylar
SDN-06	6 mm	Steel	10^6 (1,000,000)	Tyvek/Mylar

Spore Discs - Hydrogen Peroxide
Geobacillus stearothermophilus 12 month shelf-life

NAMSA Code	Disc Diameter	Carrier Type	Spore Population / Disc	Packaging
GFS-06	9 mm	Glass fiber	10^6 (1,000,000)	Bulk
GFTS-06	9 mm	Glass fiber	10^6 (1,000,000)	Tyvek/Mylar
SDS-06	6 mm	Steel	10^6 (1,000,000)	Tyvek/Mylar

Spore Ampoules

NAMSA offers spore ampoules for use in monitoring the efficacy of steam sterilization processes. Spore ampoules are a self contained biological indicator ideal for use in validation of liquid sterilization cycles. Ampoules may be placed in larger containers such as vials but are also suitable for monitoring non-liquid loads. No activation is required after exposure of the spore ampoule to a sterilization process. Remove the ampoule post exposure from the sterilizer and incubate.

Spore ampoules are manufactured using hermetically sealed Type I borosilicate glass containing a modified Soybean Casein Digest Broth with pH indicator and the specified population of *Geobacillus stearothermophilus* or *Bacillus subtilis* spores. Growth is evident by either turbidity and/or a shift in color. Spore ampoules are labeled with 24 months of shelf life. Store ampoules under refrigerated conditions (5 ± 3°C). Spore ampoules are compliant with ANSI/AAMI/ISO/EN and USP where applicable.

Spore ampoules are available in several configurations. Please inquire for additional population levels and availability.

Spore Ampoules

Geobacillus stearothermophilus 24 month shelf-life

NAMSA Code	Population	Product Description	Packaging
SA1-15-05	10^5	1 mL	15/box
SA1-50-05	10^5	1 mL	50/box
SA1-15-06	10^6	1 mL	15/box
SA1-50-06	10^6	1 mL	50/box

Negative Controls

24 month shelf-life

NAMSA Code	Population	Product Description	Packaging
SA1-NC-10	NA	1 mL Control	10/box

Mini-Spore Ampoules

Geobacillus stearothermophilus 24 month shelf-life

NAMSA Code	Population	Product Description	Packaging
OS1-50-06	10^6	0.4 mL	50/box + 5 negative controls

Mini-Spore Ampoules

Bacillus Subtilis 24 month shelf-life

NAMSA Code	Population	Product Description	Packaging
BS-100	10^6	0.4 mL	100/box + 10 negative controls

Spore Suspensions

NAMSA Spore Suspensions are pure suspensions of viable spores with known resistance characteristics and population levels. The convenience of the Spore Suspensions allows for direct inoculation of products, typically to verify sterility of devices where a traditional BI 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.

NAMSA Spore Suspensions are packaged in 10 mL volumes and are sold in pharmaceutical grade glass vials with screw cap and septum which allows for withdrawal of the suspension using either a pipette or a needle and syringe assembly. The spores are suspended in Water for Injection (WFI) in a variety of population levels standardized per 0.1 mL. Spore Suspensions manufactured with WFI and ethanol or population levels below 10^6 are also available upon request; please contact NAMSA for pricing, lead time and availability.

NAMSA Spore Suspensions are ANSI/AAMI/ISO EN 11138-1 and USP (where applicable) compliant. The Suspensions are labeled with a shelf life based on the organism. Spore Suspensions require storage under refrigerated conditions (2° - 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.

Ethylene Oxide or Dry Heat

Bacillus atrophaeus 18 month shelf-life

NAMSA Code	Spore Population Per 0.1 mL
SUN - 06	10^6 (1,000,000)
SUN - 07	10^7 (10,000,000)
SUN - 08	10^8 (100,000,000)

Steam

Geobacillus stearothermophilus 24 month shelf-life

NAMSA Code	Spore Population Per 0.1 mL
SUS - 06	10^6 (1,000,000)
SUS - 07	10^7 (10,000,000)
SUS - 08	10^8 (100,000,000)

Bacillus subtilis Cell Line 5230
15 month shelf-life

NAMSA Code	Spore Population Per 0.1 mL
US52306	10^6 (1,000,000)
US52307	10^7 (10,000,000)
US52308	10^8 (100,000,000)

Bacillus subtilis Cell Line 6633
14 month shelf-life

NAMSA Code	Spore Population Per 0.1 mL
SBS - 06	10^6 (1,000,000)
SBS - 07	10^7 (10,000,000)
SBS - 08	10^8 (100,000,000)

Radiation

Bacillus pumilus 24 month shelf-life

NAMSA Code	Spore Population Per 0.1 mL
SUP-06	10^6 (1,000,000)
SUP-07	10^7 (10,000,000)
SUP-08	10^8 (100,000,000)

CHEMICAL INDICATORS

NAMSA Chemical Process Indicators are self-adhesive labels manufactured with water based, environmentally friendly inks containing no lead or other heavy metals and low VOC's. The indicators are suitable for application by hand or Meto® gun on shipping cartons or individual packages. The label color indicates at a glance whether or not the product has been exposed to a specific process. Brilliant color transitions make it easy for sterilization facilities and manufacturers to control inventory and provide assurance to end users that products have been exposed to the process.

Radiation Chemical Process Indicators

NAMSA Radiation Chemical Process Indicators (CPIs) are manufactured to meet performance specifications described in ANSI/AAMI/ ISO 11140-1 "Sterilization of health care products - Chemical indicators - Part 1: General Requirements," for Class 1 Process Indicators. The color transitions are dose dependent (see chart to the right). NAMSA Radiation CPIs are not intended for use as dosimeters, but rather as throughput process indicators used to monitor exposure to radiation processes. NAMSA Radiation CPIs are intended for use in gamma or e-beam radiation sterilization processes.

NAMSA Radiation CPIs are labeled with 24 months of shelf life and room temperature storage (23 ± 7° C). The shelf life is based on the date the indicating ink is applied to the substrate. Product may have a shelf life of less than 24 months at the time of purchase. Moderate heat (up to 35° C) will not adversely affect indicators performance. Labeled storage conditions should be observed at all times to maintain optimum sensitivity. Avoid contact or storage of indicators near flourescent lighting and direct sunlight which are forms of radiation.

Exposed indicators are stable and remain the signal color when stored under labeled conditions. Each roll is individually packaged with a certificate of conformance to ensure the products' quality and consistency.

NAMSA Radiation CPIs are non-odorous and non-hazardous to use. The printed labels are safe to dispose in general waste receptacles. No MSDS required per CFR.1910.1200.

Process Indicator Configurations

NAMSA Code	Product Type	Dose Level	Number of Indicators / Roll	Example
CPI-R01	Plain 1/2" (12.7 mm) circles	≥10kGy	5,000	
CPI-R02	Meto® gun indicators for hand-held labeling systems	≥10 kGy	1,000	
CPI-R03	Imprinted 1/2" (12.7 mm) circles. Text reads: "Red is Exposed."	≥10 kGy	5,000	
CPI-F01	Low dose. Plain 1/2" (12.7mm circles)	≥3 kGy	5,000	
CPI-R06	Meto® gun indicators for hand-held labeling systems	>10 kGy	1,000	

Product Color Change Performance[1]
NAMSA Radiation Chemical Process Indicators

Product CPI-R01			
Unexposed		1 kGy[3]	
UV Light[2] 20 Minutes		10 kGy	
Product CPI-F01			
Unexposed		1 kGy[3]	
UV Light[2] 20 Minutes		10 kGy	

1 Samples are representative of performance according to ISO 11140-1 for Class 1 Process Indicators.

2 The ultraviolet radiation that is designed to show the indicator does not change color when exposed to short periods of non-ionizing radiation such as sunlight.

3 No change or a change that is markedly different from the visible change to red or violet is expected after exposure to a dose level of 1 kGy.

Ethylene Oxide Chemical Process Indicators

NAMSA Ethylene Oxide (EO) Chemical Process Indicators (CPIs) are manufactured to meet performance specifications described in ISO 11140-1 "Sterilization of health care products - Chemical indicators - Part 1: General requirements," for Class 1 Process Indicators. The purple-to-green color transition is sensitive to time, temperature, humidity and presence of EO (see chart to right). NAMSA EO CPIs are not intended for use as sterility indicators, but rather as throughput process indicators used to monitor exposure to EO sterilization processes.

NAMSA EO CPIs are labeled with 24 months of shelf life and room temperature storage (23 ± 7°C). The shelf life is based on the date the indicating ink is applied to the substrate. Product may have a shelf life of less than 24 months at the time of purchase. Avoid contact or storage of indicators near substrates which are acidic or basic in nature, such as cleaning solutions and disinfectants.

Exposed indicators are stable and will remain green when stored under labeled conditions. Each roll is individually packaged with a certificate of conformance to ensure the products' quality and consistency.

NAMSA EO CPIs are non-odorous and non-hazardous to use. The printed labels are safe to dispose in general waste receptacles. No MSDS required per CFR 1910.1200.

Process Indicator Configurations

NAMSA Code	Product Type	Number of Indicators / Roll	Example
CPI-E01	Plain 1/2" (12.7 mm) circles	5,000	
CPI-E02	Meto® gun indicators for hand-held labeling systems	1,500	
CPI-E03	Imprinted 1/2" (12.7 mm) circles. Text reads: "Green is Exposed."	5,000	
SP-E16	Imprinted Meto® gun indicators for hand-held labeling systems Text reads: "Green is Exposed."	1,500	

Product Color Change Performance[1]

NAMSA Radiation Chemical Process Indicators

Product CPI-R01

Unexposed		600 mg/L 54° C 60% RH 2 minutes[3]	
0 mg/L 60° C >85% RH 90 minutes[2]		600 mg/L 54° C 60% RH 20 minutes[4]	

1 Samples are representative of performance according to ISO 11140-1, for Class 1 Process Indicators.

2 After exposure to 0 mg/L Ethylene Oxide at 60˚C ±2˚C at greater than 85% relative humidity (RH) for not less than 90 minutes, the indicator shall show either no change or a change that is markedly different from the change occurring after exposure to an ethylene oxide sterilization process.

3 The endpoint indicating exposure to an ethylene oxide sterilization process will not occur until the indicator has been exposed to 600 ±30mg/L ethylene oxide and 60 ±10% RH at 54˚C ± 1˚C for not less than 2 minutes.

4 The endpoint indicating exposure to an ethylene oxide sterilization process shall occur when the indicator has been exposed to 600 ± 30 mg/L ethylene oxide and 60 ± 10% RH at 54˚C ±1˚C for a period not exceeding 20 minutes.

Dry Heat Chemical Process Indicators

NAMSA Dry Heat Chemical Process Indicators (CPIs) are designed to signal, through a transition in color, when exposed to high temperatures such as dry heat and steam sterilization or depyrogenation processes. The CPIs will transition from the initial to the signal color depending on the temperature and length of exposure (see chart to the right).

The CPIs are manufactured to meet the requirements of NAMSA's Quality System and where applicable have been validated per the standard depyrogenation cycles outlined in USP. NAMSA is an ISO 13485 certified and ISO 17025 accredited facility. Depyrogenation CPIs are not intended to verify sterility or endotoxin levels, but rather to indicate exposure to high temperature processes.

NAMSA CPIs are labeled with 24 months of shelf life at room temperature storage (23 ± 7°C). The shelf life is based on the date the indicating ink is applied to the substrate. Product may have a shelf life of less than 24 months at the time of purchase.

Exposed indicators are stable and will remain the signal color when stored under labeled conditions. Each roll is packaged individually and is accompanied by a certificate of conformance. Each lot of CPIs is tested to ensure the products' quality, consistency and compliance to NAMSA's label claims.

NAMSA high temperature CPIs are non-odorous and non-hazardous to use. The printed labels are safe to dispose in general waste receptacles. No MSDS required per CFR 1910.1200.

Process Indicator Configurations

NAMSA Code	Product Type	Temp.	Number of Indicators / Roll	Example
CPI-DP1	Plain 1/2" (12.7 mm) circles	≤ 250°C	500	
CPI-DH01	Plain 1/2" (12.7 mm) circles	≤ 180°C	1,000	

Product Color Change Performance[1]
NAMSA Depyrogenation Chemical Process Indicators

Product CPI-DP1

Unexposed		3 Hours at 180°C	
30 minutes at 250°C		1 Hour at 250°C	

Product Color Change Performance
NAMSA Dry Heat Chemical Process Indicators

Product CPI-DH01

Unexposed		Dry Heat 160°C 10 minutes	

1 Samples are representative of performance based on General chapters: <151> Pyrogen Test

Steam Chemical Process Indicators

NAMSA Steam Chemical Process Indicators (CPIs) are manufactured to meet performance specifications described in ISO 11140-1 "Sterilization of health care products - Chemical indicators - Part 1: General requirements," for Class 1 Process Indicators. The blue-to-pink color transition is sensitive to time, temperature and the presence of saturated steam (see chart to right). NAMSA Steam CPIs are not intended for use as sterility indicators, but rather as throughput process indicators used to monitor exposure to steam sterilization processes.

NAMSA Steam CPIs are labeled with 24 months of shelf life and room temperature storage. The shelf life is based on the date the indicating ink is applied to the substrate. Product may have a shelf life of less than 24 months at the time of purchase. Labeled storage conditions should be observed at all times to maintain optimum sensitivity.

Exposed indicators are stable and will remain pink when stored under labeled conditions. Each roll is individually packaged with a certificate of conformance to ensure the products' quality and consistency.

NAMSA Steam CPIs are non-odorous and non-hazardous to use. The printed labels are safe to dispose in general waste receptacles. No MSDS required per CFR 1910.1200.

Process Indicator Configurations

NAMSA Code	Product Type	Number of Indicators / Roll	Example
CPI-S01	Plain 1/2" (12.7 mm) circles	5,000	
SP-S05	2.5" x 1.5" label with indicator	1,000	

Product Color Change Performance[1]
NAMSA Steam Chemical Process Indicators

Product CPI-S01

Unexposed		Dry Heat[2] 140°C 30 minutes	
Saturated Steam[3] 121°C - 3 minutes		Saturated Steam[3] 134°C - 0.5 minutes	
Saturated Steam[4] 121°C - 10 minutes		Saturated Steam[4] 134°C - 2 minutes	

1 Samples are representative of performance according to ISO 11140-1, for Class 1 Process Indicators.

2 After exposure to a dry heat process at 140°C for 30 minutes, the indicator shall show either no change or a change that is markedly different from the change occuring after exposure to a steam process.

3 After exposure to shortened steam cycles, a change to pink similar to Pantone® 677 C or lighter can be expected.

4 After exposure to a steam sterilization process, an endpoint color of pink similar to Pantone® 684 C or darker can be expected.

Hydrogen Peroxide Chemical Process Indicators

NAMSA Hydrogen Peroxide Chemical Process Indicators (CPIs) are manufactured to meet performance specifications as described in ISO 11140-1 "Sterilization of health card products - Chemical indicators - Part 1: General Requirements," for Class 1 Process Indicators. NAMSA Hydrogen Peroxide CPIs are not intended for use as sterility indicators, but rather as throughput process indicators used to monitor exposure to hydrogen peroxide sterilization processes.

NAMSA Hydrogen Peroxide CPIs are labeled with 24 months of shelf life and room temperature storage. The shelf life is based on the date the indicating ink is applied to the substrate. Product may have a shelf life of less than 24 months at the time of purchase. Humid or moist environmental conditions may adversely effect the function of the Hydrogen Peroxide CPIs. Labeled storage conditions should be observed at all times to maintain optimum sensitivity.

Exposed indicators are stable and remain blue when stored under labeled conditions. A minimum of 6.0 mg/l of hydrogen peroxide is recommended for sufficient endpoint color. Each roll is individually packaged with a certificate of conformance to ensure the products' quality and consistency.

NAMSA Hydrogen Peroxide CPIs are non-odorous, and non-hazardous to use. The printed labels are safe to dispose in general waste receptacles. No MSDS required per CFR 1910.1200.

Process Indicator Configurations

NAMSA Code	Product Type	Number of Indicators / Roll	Example
CPI-P03	Imprinted 1/2" (12.7 mm) circles	5,000	

Product Color Change Performance
NAMSA Hydrogen Peroxide Chemical Process Indicators

Product CPI-DP1

Unexposed		Exposed 7 seconds at 50°C	
Absence of H_2O_2 50°C - 45 minutes		Exposed 6 minutes at 50°C	

Custom Indicator Labels

NAMSA Custom Indicator Labels save time and money by combining multiple labels into one unified label reducing application time and effort. Custom Indicator Labels can be manufactured in any size or shape with preferred indicator colors. Any of the vibrant color transitions available can be used to manufacture a custom label. NAMSA Custom Indicator Labels are available for Dry Heat, EO, Hydrogen Peroxide, Radiation, Steam and Steam-Formaldehyde processes.

Labels may include verbiage, logos, or blank areas for printing lot specific information. Custom Indicator Labels can be manufactured using a variety of substrates including laser or thermal transfer label stock and Tyvek.

NAMSA also offers Sterilization Indicating Inks in most of the color combinations outlined. Please inquire for distribution information.

Available Indicating Inks for Use on Base Stocks

Process	Initial Color	Signal Color
Dry Heat	Yellow	Green
	Uncolored	Blue
	Pink	Violet
	Orange	Brown
	Gray	Blue
EO	Violet	Green
	Yellow	Blue
	Yellow	Brown
	Red	Green
	Red	Yellow
	Blue	Green
Hydrogen Peroxide	Red	Yellow
	Blue	Pink
	Violet	Pink
	Red	Blue
	Yellow	Blue
	Blue	Green
Radiation	Yellow	Red
	Green	Violet
Steam	Blue	Pink
	White	Brown
Steam Formaldehyde	Violet	Green

Growth Promotion Test Suspensions

Growth Promotion Test Suspensions provide a quality control challenge to each batch or lot of medium, ensuring its growth promoting qualities, whether it is prepared internally from basic ingredients or purchased commercially prepared. Inoculate each batch or lot of medium, directly without rehydration, dilution or reconstitution. Visible growth after incubation indicates the culture media is conducive to organism growth.

NAMSA Growth Promotion Test Suspensions are ready-to-use microbial suspensions that meet the requirements of USP <71> Sterility Test. All suspensions comply with the requirement for population of <100 colony forming units (CFU) and are guaranteed to be within five passages of an original stock culture. All Growth Promotion Test Suspensions are provided as pure cultures in 2.5 mL or 10 mL volumes containing 25 or 100 doses (0.1 mL each). Store suspensions under refrigerated conditions 5˚C ± 3˚C.

Growth Promotion Test Suspensions are sold in glass vials with screw-top caps containing a septum. The screw-top cap with septum allows for access using either a pipette or a needle and syringe.

The organisms can be used to manufacture suspensions with population levels up to 10^6 /0.1 mL or higher. Please inquire for information on population levels greater than 100 colony forming units (CFU's) /0.1 mL for the Growth Promotion organisms.

Growth Promotion Test Suspensions

NAMSA Code		Organism	Shelf-Life
10 ml	**2.5 ml**		
GP-01	GP25-01	Bacillus subtilis	14 months
GP-02	GP25-02	Clostridium sporogenes	14 months
GP-03	GP25-03	Candida albicans	12 weeks
GP-04	GP25-04	Aspergillus brasiliensis[1]	7 months
GP-05	NA	Kocuria rhizophila	16 weeks
GP-06	NA	Geobacillus stearothermophilus	24 months
GP-07	GP25-07	Pseudomonas aeruginosa	8 weeks
GP-08	GP25-08	Staphylococcus aureus	8 weeks
NA	GP25-09	Escheria coli	10 weeks
GP-10	NA	Bacillus atrophaeus	18 months
NA	GP25-11	Salmonella enterica	12 weeks

1 Formerly known as *Aspergillus niger*

NA = Configuration not available

Sterilization Monitoring Products Testing Services

Biological Indicator Performance Tests - Resistance

TEST DESCRIPTION	CODE
Ethylene Oxide D-value - FPN Method in Resistometer	L0034-104
Survival / Kill Tests, USP Ethylene Oxide - Resistometer	
Survival & Kill Time Verification	L0034-101
Survival Time Verification Only	L0034-102
Kill Time Verification Only	L0034-103
Steam D-value - FPN Method in Resistometer	L0035-104
Survival / Kill Tests, USP Steam - Resistometer	
Survival & Kill Time Verification	L0035-101
Survival Time Verification Only	L0035-102
Kill Time Verification Only	L0035-103
Dry Heat D-value - FPN Method in Laboratory Oven	L0036-104
Survival / Kill Tests, USP Dry Heat - Laboratory Oven	
Survival & Kill Time Verification	L0036-101
Survival Time Verification Only	L0036-102
Kill Time Verification Only	L0036-103
D-value Studies - Survivor Curve / Total Plate Count Method	M/S
Validation of Reduced Biological Indicator Incubation Time (RIT) per CDRH	ADMIN_RDH

Biological Indicator Performance Tests - Population Verification

TEST DESCRIPTION	CODE
Total Viable Spore Count - One Species, Heat Shock (Three Samples)	L0031-100

Microbial Identification

TEST DESCRIPTION	CODE
Microbial Identification for Bacteria/Yeast (Vitek II)	MG010
ID of Microorganisms - Mold	MG048

Chemical Indicator ISO 11140-1 Class Characterization

TEST DESCRIPTION	CODE
Steam	ADMIN_RDH
Ethylene Oxide (EO)	ADMIN_RDH
Dry Heat	ADMIN_RDH
Steam Formaldehyde	ADMIN_RDH
Radiation	ADMIN_RDH
Vaporized Hydrogen Peroxide	ADMIN_RDH

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