Excelsior Scientific

Sterilisation Monitoring Products

Known for their consistent, reliable performance, Excelsior sterilisation monitoring products are used by pharmaceutical and medical device manufacturers, contract sterilisers, and other related industries.

These products are used to:

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

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

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Excelsior Scientific

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Bowie & Dick Tests

Excelsior offers Bowie & Dick Test packs for monitoring steam sterilisation processes using autoclaves. The Bowie Dick Test Pack consists of a series of steam penetration (air removal) barriers in the centre of which is a chemical indicator sheet. The test pack should be placed into an empty autoclave chamber and put through a recommended autoclave cycle of 134°C for 3.5 minutes.

During processing, the cycle must remove or displace the air from within the barrier material, and replace it with steam throughout the pack. A uniform change from blue to pink indicates adequate steam penetration. The thermochromic ink formulation detects problems with steam quality and can used a diagnostic tool by an autoclave engineer.

These can be used to qualify a newly installed autoclave or following a major repair but are generally used to monitor performance changes in air removal and steam quality during routine use.

Excelsior Bowie Dick Tests are not hazardous, products according to the OSHA Hazard communication standard, 29 CFR 1910.1200 and are free of lead and other heavy metals.

Catalogue No.	Description
BD-1XCS	Bowie & Dick Test Pack, Single Use (without heavy metals) Conforms to EN 867-4 For use at Steam 134°C for 3 – 3.5 minutes 20 Test Packs/Case
BD-1X	Bowie & Dick Test Pack, Single Use (without heavy metals) Conforms to EN 867-4 For use at Steam 134°C for 3 – 3.5 minutes Individual Test Packs

Self-Contained Biological Indicators (SCBI)

Excelsior offers Self-Contained Biological Indicators (SCBI) for monitoring steam sterilisation processes in spore population levels of 105 and 106 and for Ethylene Oxide (EO) and Hydrogen Peroxide processes in a 106 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 sterilisation 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 colour shift of the media. SCBIs are labelled with the shorter shelf life of the two components; the inoculated disc and ampoule which have independent expiration periods. Store under room temperature (15ºC - 30ºC) conditions. SCBIs are offered in boxes of 50 units. Each box is accompanied by a Certificate of Analysis and Instructions for Use. Excelsior SCBIs are compliant with ANSI/AAMI/ ISO/EN 11138-1 and USP where applicable.

Self-Contained Biological Indicators

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

Incubators

Catalogue No.	Description
INC-13A	Incubator, 120v,5 - 70ºC For use in the Americas
INC-13E	Incubator, 240v,5 - 70ºC For use in Europe
INC-13U	Incubator, 240v,5 - 70ºC For use in UK

Excelsior offers aluminium dry-block incubators for use in conjunction with the SCBIs and spore ampoules. They offer an ambient to 70º C temperature range with a tolerance of ±2º C. The incubator has a removable, clear poly-carbonate 10-well rack allowing for full viewing of all units at a glance.

Spore Strips

Excelsior 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 102 to 108 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 labelled 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). Excelsior 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

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

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

Bacillus subtilis 15 month shelf-life

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

Radiation
Bacillus pumilus 24 month shelf-life

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

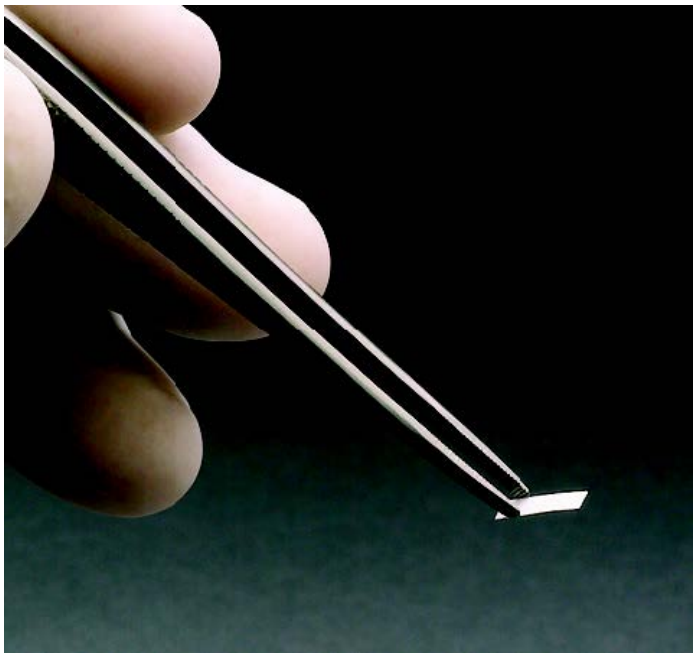
Code	Spore Population Per Strip
STNS-65	10^5 (100,000) Geobacillus stearothermophilus 10^6 (1,000,000) Bacillus atropheaus

Dry Heat
Bacillus atrophaeus 24 month shelf-life

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 labelled 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). Excelsior 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

Code	Packaging	Spore Population Per 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

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

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

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

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

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

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

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

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

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 12 month shelf-life

Code	Length	Carrier Type	Spore Population Per Strip	Packaging
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 labelled 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). Excelsior 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

Code	Length	Carrier Type	Spore Population Per Strip	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

Code	Length	Carrier Type	Spore Population Per Strip	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

Code	Length	Carrier Type	Spore Population Per Strip	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
GTFN-05	9 mm	Glass fiber	10^5 (100,000)	Tyvek / Mylar
GTFN-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

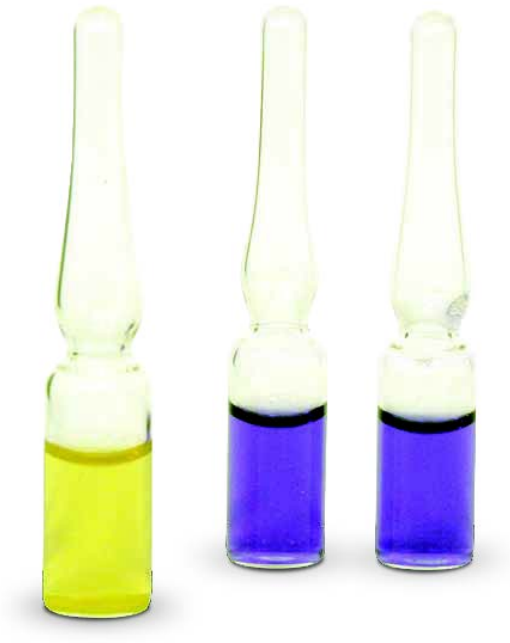
Code	Length	Carrier Type	Spore Population Per Strip	Packaging
GFS-06	9 mm	Glass fiber	10^6 (1,000,000)	Bulk
GFTS-06	9 mm	Glass fiber	10^6 (1,000,000)	Tyvek / Mylar
SDS-06	6 mm Steel	Steel	10^6 (1,000,000)	Tyvek / Mylar

Spore Ampoules

Excelsior offers spore ampoules for use in monitoring the efficacy of steam sterilisation processes. Spore ampoules are a self contained biological indicator ideal for use in validation of liquid sterilisation 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 sterilisation process. Remove the ampoule post exposure from the steriliser 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 colour. Spore ampoules are labelled 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

Code	Population	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

Code	Population	Description	Packaging
SA1-NC-10	N/A	1 mL Control	10/box

Mini-Spore Ampoules
Geobacillus stearothermophilus 24 month shelf-life

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

Mini-Spore Ampoules
Bacillus Subtilis 24 month shelf-life

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

Spore Suspensions

Excelsior 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.

Excelsior 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 106 are also available upon request; please contact Excelsior for pricing, lead time and availability.

Excelsior Spore Suspensions are ANSI/AAMI/ISO EN 11138-1 and USP (where applicable) compliant. The Suspensions are labelled with a shelf life based on the organism.

Ethylene Oxide or Dry Heat
Bacillus atrophaeus 18 month shelf-life

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

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

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

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

Radiation
Bacillus pumilus 24 month shelf-life

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

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.

Excelsior 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 colour indicates at a glance whether or not the product has been exposed to a specific process. Brilliant colour transitions make it easy for sterilisation facilities and manufacturers to control inventory and provide assurance to end users that products have been exposed to the process.

Radiation Chemical Process Indicators

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

Excelsior Radiation CPIs are labelled 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. Labelled storage conditions should be observed at all times to maintain optimum sensitivity. Avoid contact or storage of indicators near fluorescent lighting and direct sunlight which are forms of radiation.

Process Indicator Configurations

Code	Product Type	Dose Level	Number of CPI’s / Roll	Example
CPI-R01	Plain 1/2” (12.7mm)	≥10 kGy	5,000	
CPI-R02	METO® gun indicators for hand-held labelling systems	≥10 kGy	1,000	
CPI-R03	Imprinted 1/2” (12.7mm) circles Text reads: “Red is Exposed”	≥10 kGy	5,000	
CPI-F01	Low dose Plain 1/2” (12.7mm)	≥3 kGy	5,000	
CPI-R06	METO® gun indicators for hand-held labelling systems	≥10 kGy	1,000	

Product Colour Change Performance [1] Excelsior Radiation Chemical Process Indicators

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

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

Excelsior 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.

Ethylene Oxide Chemical Process Indicators

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

Excelsior EO CPIs are labelled 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.

Process Indicator Configurations

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

Product Colour Change Performance [1]
Excelsior Radiation Chemical Process Indicators

Product CPI-E01

Unexposed		600 mg/L 54ºC 60% RH 2 minutes [3]	
0 mg/L 60ºC >85% RH 90 minutes [2]		600 mg/L 54ºC 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 sterilisation 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 sterilisation 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.

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

Excelsior 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.

Dry Heat Chemical Process Indicators

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

The CPIs are manufactured to meet the requirements of Excelsior's manufacturing partner's Quality System and where applicable have been validated per the standard depyrogenation cycles outlined in USP. Excelsior's manufacturing partner 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.

Process Indicator Configurations

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

Product Colour Change Performance [1]
Excelsior Depryrogenation Chemical Process Indicators

Product CPI-DP1

Unexposed		3 Hours at 180ºC	
30 mins. at 250ºC		1 Hour at 250ºC	

Product Colour Change Performance
Excelsior Dry Heat Chemical Process Indicators

Product CPI-DH01

Unexposed		Dry Heat 160ºC 10 minutes	

1 Samples are representative of performance based on general chapters <151> pyrogen test.

Excelsior CPIs are labelled 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 colour when stored under labelled 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 Excelsior's label claims.

Excelsior 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.

Steam Chemical Process Indicators

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

Excelsior Steam CPIs are labelled 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. Labelled storage conditions should be observed at all times to maintain optimum sensitivity.

Process Indicator Configurations

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

Product Colour Change Performance [1] Excelsior Steam Chemical Process Indicators

Product CPI-S01

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

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 occurring 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 colour of pink similar to Pantone® 684 C or darker can be expected.

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

Excelsior 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

Hydrogen Peroxide Chemical Process Indicators

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

Process Indicator Configurations

Code	Product Type	Number of CPI’s / Roll	Example
CPI-P03	Imprinted 1/2” (12.7mm) circles	5,000	

Product Colour Change Performance
Excelsior Steam 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	

Excelsior Hydrogen Peroxide CPIs are labelled 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. Labelled storage conditions should be observed at all times to maintain optimum sensitivity.

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

Excelsior 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

Custom Indicator Labels

Excelsior 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 colours. Any of the vibrant colour transitions available can be used to manufacture a custom label. Excelsior 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.

Excelsior also offers Sterilisation Indicating Inks in most of the colour combinations outlined. Please inquire for distribution information.

Available Indicating Inks for Use on Base Stocks

Process	Initial Colour	Signal Colour
Dry Heat	Yellow Uncoloured Pink Orange Grey	Green Blue Violet Brown Blue
EO	Violet Yellow Yellow Red Red Blue	Green Blue Brown Green Yellow Green
Hydrogen Peroxide	Red Blue Violet Red Yellow Blue	Yellow Pink Pink Blue Blue Green
Radiation	Yellow Green	Red Violet
Steam	Blue White	Pink 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.

Excelsior 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 106 /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

Code 10ml	Code 2.5 ml	Organism	Shelf Life
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	N/A	Kocuria rhizophila	16 weeks
GP-06	N/A	Geobacillus stearothermophilus	24 months
GP-07	GP25-07	Pseudomonas aeruginosa	8 weeks
GP-08	GP25-08	Staphylococcus aureus	8 weeks
N/A	GP-25-09	Escherichia coli	10 weeks
GP-10	N/A	Bacillus atrophaeus	18 months
N/A	GP-25-11	Salmonella enterica	12 weeks

1 Formerly known as *Aspergillus niger*

NA = Configuration not available

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