



**Excelsior
Scientific**



STERILISATION MONITORING PRODUCTS



Known for their consistent, reliable performance, Excelsior Scientific 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.

TABLE OF CONTENTS

Bowie-Dick Tests

Bowie-Dick Tests **3**

Biological Indicators

Self-Contained Biological Indicators (SCBI) **4**

Spore Ampoules & Incubators **5**

Spore Strips **6**

Mini Spore Strips **7**

Custom Biological Indicators **8**

Spore Discs **9**

Suspensions

Spore Suspensions **10**

Growth Promotion Test Suspensions **11**

Chemical Indicators

Radiation **13**

Ethylene Oxide **14**

Dry Heat **15**

Steam **16**

Hydrogen Peroxide **17**

Indicator Tapes **18**

Test Strips **19**



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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 or 121°C for 15 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 be used as a diagnostic tool.

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-1XECS	Bowie-Dick Test Pack, Single Use (without heavy metals) Conforms to EN 867-4. For use at steam 134°C for 3.5 minutes or 121°C for 15 minutes. 20 Test Packs/Case.



SELF-CONTAINED BIOLOGICAL INDICATORS (SCBI) AND MINI SELF-CONTAINED BIOLOGICAL INDICATORS (MSCBI)



Excelsior offers Self-Contained Biological Indicators (SCBI) and Mini Self-Contained Biological Indicators (MSCBI) for monitoring steam sterilisation 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 & MSCBI unit consists of a plastic vial with a cap, a crushable glass ampoule with recovery media, and a disc inoculated with spores. SCBIs & MSCBIs 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. SCBIs and MSCBIs also offer a shortened incubation period. Traditionally this has been 24 hours, already reduced from 7 days, however Excelsior Scientific is now proud to announce that our SCBIs now offer a rapid readout.

The recovery medium consists of a modified Soybean Casein Digest Broth with pH indicator. Activate for incubation by depressing the cap completely for SCBIs, or squeezing the sides of the MSCBIs and crushing the ampoule. Growth is evident by either turbidity and/ or a colour shift of the media. SCBIs and MSCBIs 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 (15°C - 30°C) conditions. SCBIs which are 9mm x 48mm are offered in boxes of 50 units. MSCBIs which are 8.3mm x 45.8mm are offered in boxes of 100 units. Each box is accompanied by a Certificate of Analysis and Instructions for Use.

Self-Contained Biological Indicators

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

Mini Self-Contained Biological Indicators

Code	Sterilisation Process	Organism	Pop.	Min. Incubation Period
MSCS-05E	Steam	Geobacillus stearothermophilus	10^5	24 hours
MSCS-06E	Steam	Geobacillus stearothermophilus	10^6	24 hours
MSCE-06E	EO	Bacillus atrophaeus	10^6	48 hours
MSCH-06E	Hydrogen Peroxide	Geobacillus stearothermophilus	10^6	24 hours



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 & the specified population of *Geobacillus stearothermophilus*. 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 ($5 \pm 3^{\circ}\text{C}$). Spore ampoules are compliant with ANSI/AAMI/ISO/EN and USP where applicable.

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



Spore Ampoules

Geobacillus stearothermophilus 24 month shelf-life

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

Negative Controls

24 month shelf-life

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

Mini-Spore Ampoules

Geobacillus stearothermophilus 24 month shelf-life

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

INCUBATORS

Excelsior offers aluminium dry-block incubators for use in conjunction with the MSCBIs, SCBIs, and spore ampoules. They offer an ambient to 70°C temperature with a tolerance of $\pm 0.5^{\circ}\text{C}$. The 10-well incubators have removable clear polycarbonate lids and easy-read, programmable digital temperature and time displays.

Code	Description
INC-13AE	Incubator, N. American plug type. Ambient to 70°C
INC-13EE	Incubator, European plug type. Ambient to 70°C
INC-13UE	Incubator, UK plug type. Ambient to 70°C



SPORE STRIPS

Excelsior offers a full line of spore strips for use in monitoring sterilisation processes. Spore strips consist of inoculated filter paper, 6mm x 30mm, packaged in a glassine envelope. 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 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 envelope contains a BI consistent in population, purity and dimension. Spore strips are packaged in shelf packs of 100 and labelled with a 24 month shelf-life based on the organism. Store strips at 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-04E	10^4 (10,000)
STN-05E	10^5 (100,000)
STN-06E	10^6 (1,000,000)

Steam

Geobacillus stearothermophilus 24 month shelf-life

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

Steam – Low Temperature Processes

Bacillus Subtilis 24 month shelf life

Code	Spore Population Per Strip
BSS2306E	10^6 (1,000,000)

Radiation

Bacillus pumilus 24 month shelf-life

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

Combination Strips

Geobacillus stearothermophilus and
Bacillus atrophaeus 24 month shelf-life

Code	Spore Population Per Strip
STNS-65E	10^5 (100,000) <i>Geobacillus stearothermophilus</i> 10^6 (1,000,000) <i>Bacillus atrophaeus</i>

Dry Heat

Bacillus atrophaeus 24 month shelf-life

Code	Spore Population Per Strip
STN-06DHE	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 (6mm x 30mm) 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 at 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 10⁶, please enquire.

Mini Spore Strips - Steam

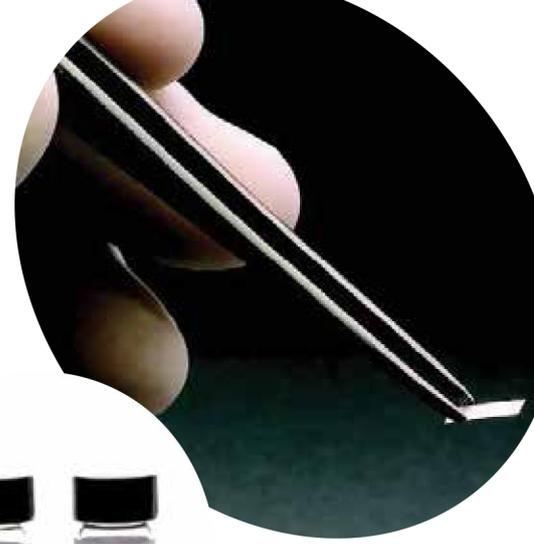
Geobacillus stearothermophilus 24 month shelf-life

Code	Packaging	Population
STS-062E	glassine envelopes	10 ⁶
STS-062BE	bulk	10 ⁶

Mini Spore Strips - Ethylene Oxide or Dry Heat

Bacillus atrophaeus 24 month shelf-life

Code	Packaging	Population
STN-062E	glassine envelopes	10 ⁶
STN-062BE	bulk	10 ⁶



PRE-PREPARED MEDIA FOR USE WITH SPORE STRIPS

Excelsior's Prepared Culture Media consists of an exclusively formulated Tryptic Soy Broth (TSB) modified with pH indicator. A reduced incubation time of 24 hours for steam, VH₂O₂ & 48 hours for ETO or Dry Heat sterilisation has been validated when the Excelsior Biological Indicator Spore Strips and Discs are used in conjunction with Excelsior's Prepared Culture Media. Supplied in 17mm x 63mm Type I borosilicate glass flat bottom tubes with screw-caps. 100 x 6.5ml tubes per box.

Code	Sterilisation Process	Organism	Incubation Time
GMBCP-100E	Steam, VH ₂ O ₂	<i>Geobacillus stearothermophilus</i>	24 hours
GMBTB-100E	ETO or Dry Heat	<i>Bacillus Atrophaeus</i>	48 hours

CUSTOM BIOLOGICAL INDICATORS



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

Spore Threads - Ethylene Oxide or Dry Heat

Bacillus atrophaeus 24 month shelf-life

Code	Length	Carrier Type	Spore Population Per Strip	Packaging
THN-06E	30 mm	Cotton thread	10 ⁶ (1,000,000)	Bulk

Spore Threads - Steam

Geobacillus stearothermophilus 24 month shelf-life

Code	Length	Carrier Type	Spore Population Per Strip	Packaging
THS-05E	30 mm	Cotton thread	10 ⁵ (100,000)	Bulk
THS-06E	30 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-06E	38 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-06E	38 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-06E	38 mm	Braided steel	10 ⁶ (1,000,000)	Bulk

Spore Strips—Chlorine Dioxide

Geobacillus stearothermophilus 24 month shelf-life

Code	Length	Carrier Type	Spore Population Per Strip	Packaging
TCDS-06E	6 x 30 mm	Filter Paper	10 ⁶ (1,000,000)	Tyvek® / Tyvek®

SPORE DISCS

Spore Discs (3 mm and 6 mm diameters) will fit into small areas of a device where a standard-sized (6mm x 30mm) 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 at 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 enquire.



Spore Discs - Ethylene Oxide or Dry Heat

Bacillus atrophaeus 24 month shelf-life

Code	Length	Carrier Type	Spore Population Per Strip	Packaging
DN-06E	6 mm	Filter paper	10 ⁶ (1,000,000)	Bulk
DN18-06E	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-06E	6 mm	Filter paper	10 ⁶ (1,000,000)	Bulk
DS18-06E	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
SDN-06E	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
SDS-06E	6 mm	Steel	10 ⁶ (1,000,000)	Tyvek® / Mylar®
TTS-06E	6 mm	Steel	10 ⁶ (1,000,000)	Tyvek® / Tyvek®



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 standardised per 0.1mL. We are also able to provide spores in WFI with up to 40% ethanol mixture upon request.

Spore Suspensions with population levels below 10^6 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.

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 Cell Line 9372, 24 month shelf-life

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

Steam

Geobacillus stearothermophilus Cell Line 7953, 24 month shelf-life

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

Bacillus Subtilis Cell Line 5230, 24 month shelf-life

Code	Spore Population Per 0.1 mL
US52306E	10^6 (1,000,000)
US52307E	10^7 (10,000,000)
US52308E	10^8 (100,000,000)

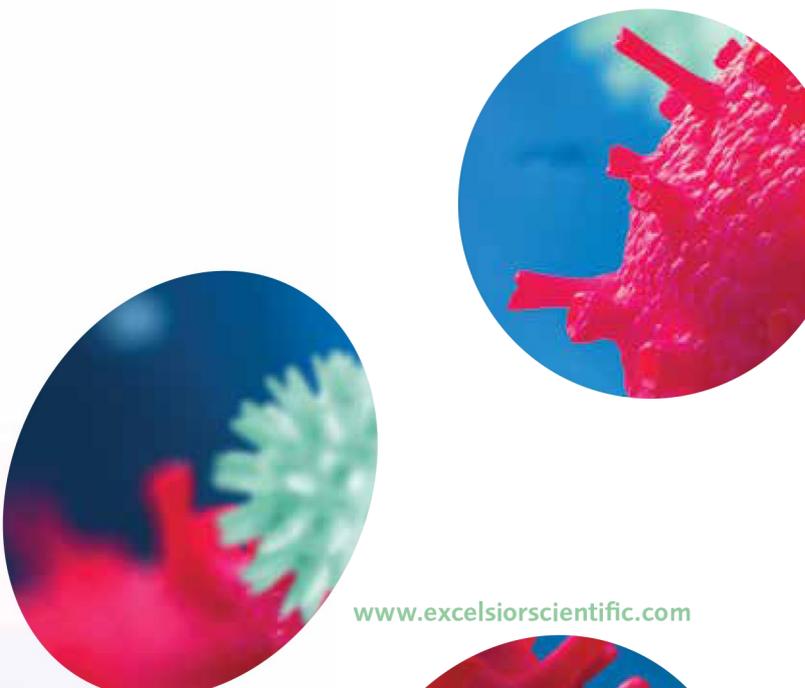
Bacillus Subtilis Cell Line 6633, 24 month shelf-life

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

Radiation

Bacillus pumilus Cell Line 27142, 24 month shelf-life

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



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 10 mL volumes containing 100 doses (0.1 mL each). Store suspensions under refrigerated conditions $5^{\circ}\text{C} \pm 3^{\circ}\text{C}$.

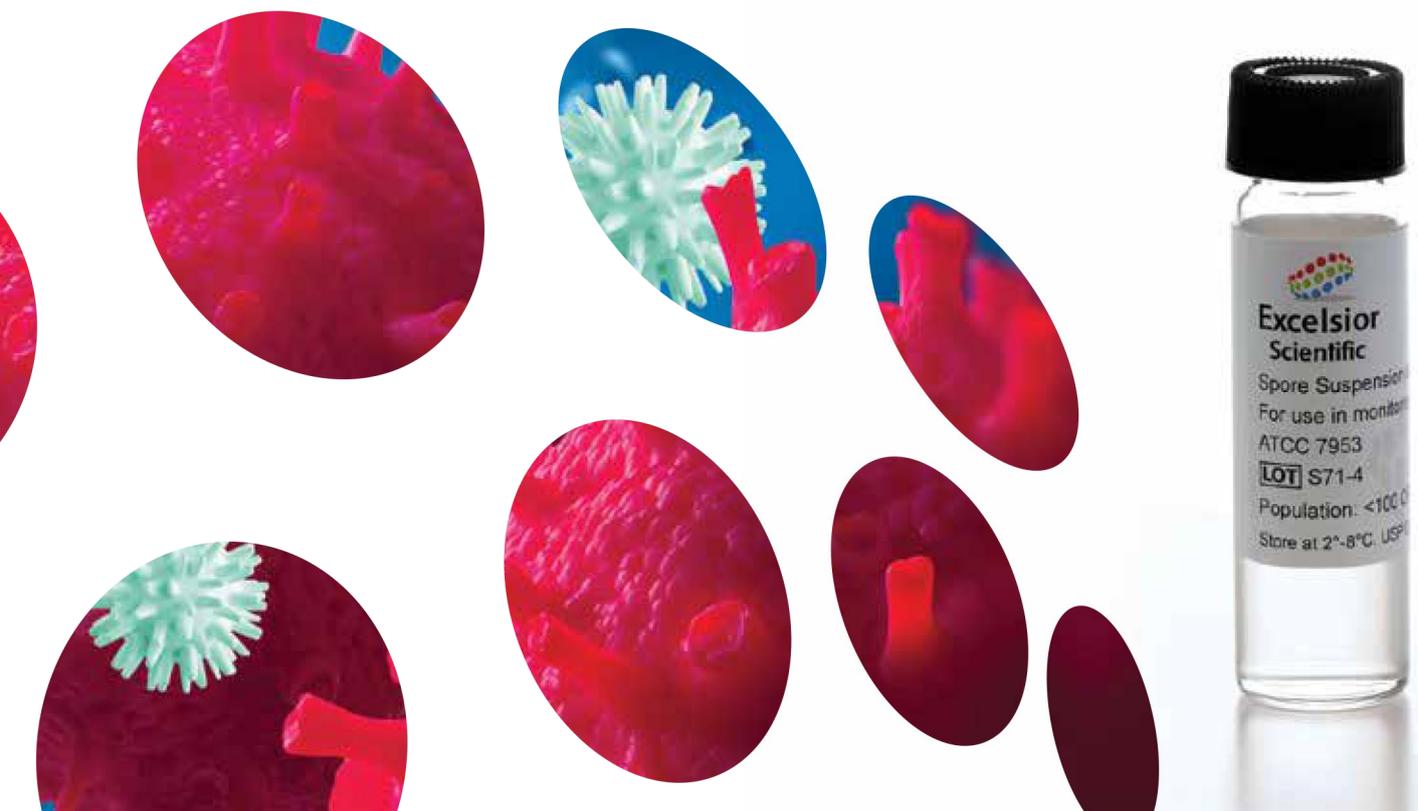
Growth Promotion Test Suspensions are sold in glass vials with screw-top caps containing a septum. The screw-top cap with septum allows for access using either a pipette or a needle and syringe.

The organisms can be used to manufacture suspensions with population levels up to 10^6 /0.1 mL or higher. Please enquire for information on population levels greater than 100 Colony Forming Units (CFUs) /0.1 mL for the Growth Promotion organisms.

Growth Promotion Test Suspensions

Code 10ml	Organism	Shelf Life
GP-01E	Bacillus subtilis (cell line 6633)	14 months
GP-06E	Geobacillus stearothermophilus (cell line 7953)	24 months
GP-10E	Bacillus atrophaeus (cell line 9372)	18 months

Many other organisms available upon special request



CHEMICAL INDICATORS

Excelsior Chemical Process Indicators are self-adhesive labels manufactured with water based, environmentally friendly inks containing no lead or other heavy metals and low VOCs. 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 & E-BEAM 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 ($23 \pm 7^\circ\text{C}$). 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.

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.

Process Indicator Configurations

Code	Product Type	Dose Level	Number of CPIs / Roll	Example
CPI-R01E	Plain 1/2" (12.7mm)	$\geq 10\text{ kGy}$	5,000	
CPI-R02E	METO® gun indicators for hand-held labelling systems	$\geq 10\text{ kGy}$	1,000	
CPI-R03E	Imprinted 1/2" (12.7mm) circles. Text reads: "Red is γ Exposed"	$\geq 10\text{ kGy}$	5,000	
CPI-R05E	Low dose, imprinted 14mm x 14mm squares. Text reads: "RED IS β EXPOSED"	$\geq 3\text{ kGy}$	5,000	
CPI-R06E	METO® gun indicators for hand-held labelling systems	$\geq 10\text{ kGy}$	1,000	

Product Colour Change Performance ¹ Excelsior Radiation Chemical Process Indicators

Product CPI-R01E			
Unexposed		1 kGy ³	
UV Light ² 20 Mins.		10 kGy	

Product CPI-R05E			
Unexposed		1 kGy ³	
UV Light ² 20 Mins.		25 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 colour when exposed to short periods of non-ionizing radiation such as sunlight.



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 ($23 \pm 7^\circ\text{C}$). 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 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.

Process Indicator Configurations

Code	Product Type	Number of CPIs / Roll	Example
CPI-E01E	Plain 1/2" (12.7mm)	5,000	
CPI-E02E	METO® gun indicators for hand-held labelling systems	1,500	
CPI-E03E	Imprinted 1/2" (12.7mm) circles. Text reads: "Red is Exposed"	5,000	

Product Colour Change Performance ¹

Excelsior Ethylene Oxide Chemical Process Indicators

Product CPI-E01E			
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 2 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 $60^\circ\text{C} \pm 2^\circ\text{C}$ 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 sterilisation process will not occur until the indicator has been exposed to $600 \pm 30\text{mg/L}$ ethylene oxide and $60 \pm 10\%$ RH at $54^\circ\text{C} \pm 1^\circ\text{C}$ 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 $600 \pm 30\text{mg/L}$ ethylene oxide and $60 \pm 10\%$ RH at $54^\circ\text{C} \pm 1^\circ\text{C}$ for a period not exceeding 20 minutes.



DRY HEAT DEPYROGENATION 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 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. Depyrogenation CPIs are not intended to verify sterility or endotoxin levels, but rather to indicate exposure to high temperature processes.

Excelsior CPIs are labelled with 24 months of shelf life at room temperature storage ($23 \pm 7^{\circ}\text{C}$). 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.

Process Indicator Configurations

Code	Product Type	Temp.	Number of CPIs / Roll	Example
CPI-DH01E	Plain 1/2" (12.7mm) circles	$\leq 180^{\circ}\text{C}$	5,000	

Product Colour Change Performance ¹

Excelsior Dry Heat and Depyrogenation Process Indicators

Unexposed	Exposed to 160°C , 40 minutes*	Exposed to 250°C , 60 minutes*
		

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



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.

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

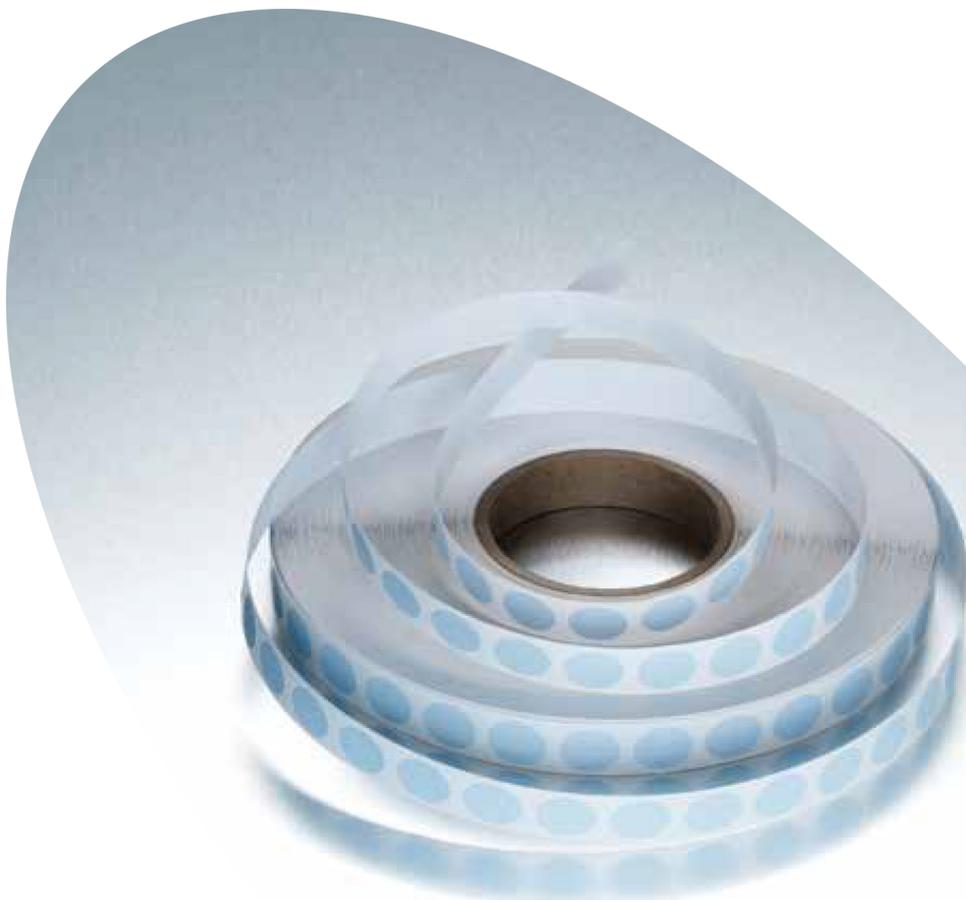
Process Indicator Configurations

Code	Product Type	Number of CPIs / Roll	Example
CPI-S01E	Plain 1/2" (12.7mm) circles	5,000	

Product Colour Change Performance ¹ Excelsior Steam Chemical Process Indicators

Product CPI-S01E			
Unexposed		Dry Heat ² 140°C 30 minutes	
Saturated Steam ³ 121°C - 3 mins.		Saturated Steam 121°C - 3 minutes	
Saturated Steam ⁴ 121°C - 10 mins.		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 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 sterilisation process, an endpoint colour of pink similar to Pantone® 684 C or darker can be expected.



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 care 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.

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.

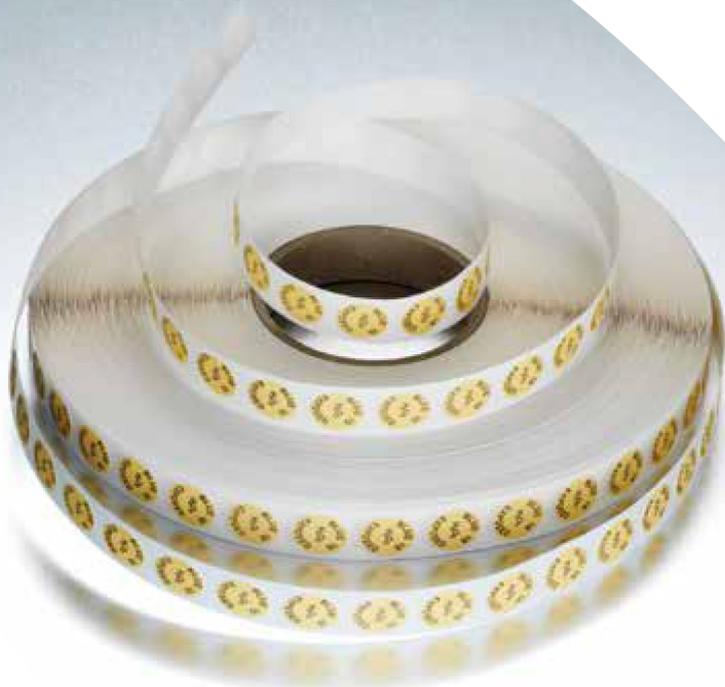
Exposed indicators are stable and remain blue when stored under labelled conditions. A minimum of 6.0 mg/l of hydrogen peroxide is recommended for sufficient endpoint colour. Each roll is individually packaged with a certificate of conformance to ensure the products' quality and consistency. Excelsior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

Process Indicator Configurations

Code	Product Type	Number of CPIs / Roll	Example
CPI-P03E	Imprinted 1/2" (12.7mm) circles	5,000	

Product Colour Change Performance Excelsior Hydrogen peroxide Chemical Process Indicators

Product CPI-P03E			
Unexposed		Exposed 7 seconds at 50°C	
Absence of H ₂ O ₂ 50°C - 45 minutes		Exposed 6 minutes at 50°C	



CHEMICAL INDICATOR TAPES

Excelsior Chemical Process Indicator Tapes are suitable for application of various types of sterilisation process including Steam, Hydrogen Peroxide (Plasma) & Ethylene Oxide. The Tape indicator colour demonstrates at a glance whether or not the product has gone through the sterilisation process, making it easy for sterilisation facilities to ensure that products have been exposed correctly to the sterilisation process.

The writing or pattern on the tapes transitions from an initial colour to a different signal colour depending on the process type. Provides clean removal from sterilised object.



SELF-SEAL AUTOCLAVE & STERILISATION POUCHES

Excelsior autoclave pouches have been designed with a special, easy to use, self seal strip, to allow for the quick and efficient autoclaving of individual items.

- pouches are self-seal: peel back, fold over and seal, no separate heat sealer required
- manufactured from 2 ply laminate, transparent film, compliant with EN868-5 and medical grade paper compliant with N868-3
- autoclavable to 121°C and 134°C
- indicators for steam and ethylene oxide sterilisation
- designed with off-set webs for easy opening and tack seals to prevent curling and reduce external contamination
- the minimum width of any seal is 6mm, tested in accordance to the requirements of Annex C EN868-5
- tamper evident
- alcohol-free
- latex free

Excelsior autoclave pouches are manufactured in a Clean Room facility, which is specified to operate at ISO Class 7 (FS 209E Class 10,000) classification, in accordance with International Standard ISO 14644-1:1999.

Tape Configurations

<p>TAP-SCS-E Steam Autoclave Tape Irreversible colour transition from white to dark. Can be written on 18mm x50m 12 rolls per pack. 3 years shelf life.</p>		 
<p>TAP-ECS-E Ethylene Oxide Tape Irreversible colour transition from purple to green. Can be written on. 19mm x55m 12 rolls per pack. 3 years shelf life.</p>		 
<p>TAP-H-E H₂O₂ Plasma Tape Irreversible colour transition from red to yellow Can be written on. 19mm x55m 12 rolls per pack. 3 years shelf life.</p>		 

Range of Sizes Available

Product code	Size	Pouches per pack	Boxes per case
L850/AE	90mm x 230mm	200	20
L850/BE	135mm x 255mm	200	15
L850/CE	190mm x 330mm	200	10
L850/DE	300mm x 460mm	200	5

CHEMICAL INDICATOR TEST STRIPS

Excelsior Chemical Process Indicator Strips are suitable for application of various types of sterilisation including Steam, Dry Heat, Hydrogen Peroxide, Ethylene Oxide & Formaldehyde. The strip indicator colour demonstrates at a glance whether or not the product has gone through the sterilisation process, making it easy for sterilisation facilities to ensure that products have been exposed correctly to the sterilisation process. Strips transition an initial colour to a different signal colour depending on the process type.

Strip Configurations

Code	Process	Description	
TST-4SE TST-4ASE	Steam	Autoclave TST Strip Type 4 indicator Requires exposure for 3.5 mins at 134°C or 15 mins at 121°C. Transitions from yellow to dark. Box of 100 or 250.	
TST-5SE	Steam	Autoclave TST Strip Type 5 integrator Requires exposure at 121°C for 16.5 minutes or 135°C for 1.2 minutes. Transitions from Pink to Dark. Box of 250.	
TST-6SE	Steam	Autoclave TST Strip Type 6 Emulator Requires exposure at 121°C for 10 minutes or 134°C for 3.5 minutes. Transitions from Blue to Dark. Box of 250.	
DH-250E	Dry Heat Depyrogenation	Dry Heat Strip Type 4 Indicator Requires exposure for 40 mins at 160°C or 60mins at 155°C. Transitions from Blue to Dark Grey. Box of 250.	
HRB-250E	Hydrogen Peroxide	VH ₂ O ₂ Plasma Type 1 Indicator Requires 50°C, 6 minutes, 2.3mg/L of vapourised hydrogen peroxide. Transitions from Brown to Green. Box of 250.	
ETO-250E	Ethylene Oxide	E.O Type 4 Indicator Requires exposure for 20 mins at 54°C at 60% RH using 600 mg/L gas. Transitions from Purple/Brown to Green. Box of 250.	
CH20-250E	Formaldehyde	Formaldehyde Type 4 Indicator Requires exposure for 15 mins at 70°C. using 1 mol/L of Formaldehyde. Transitions from Pink to Green. Box of 250.	

