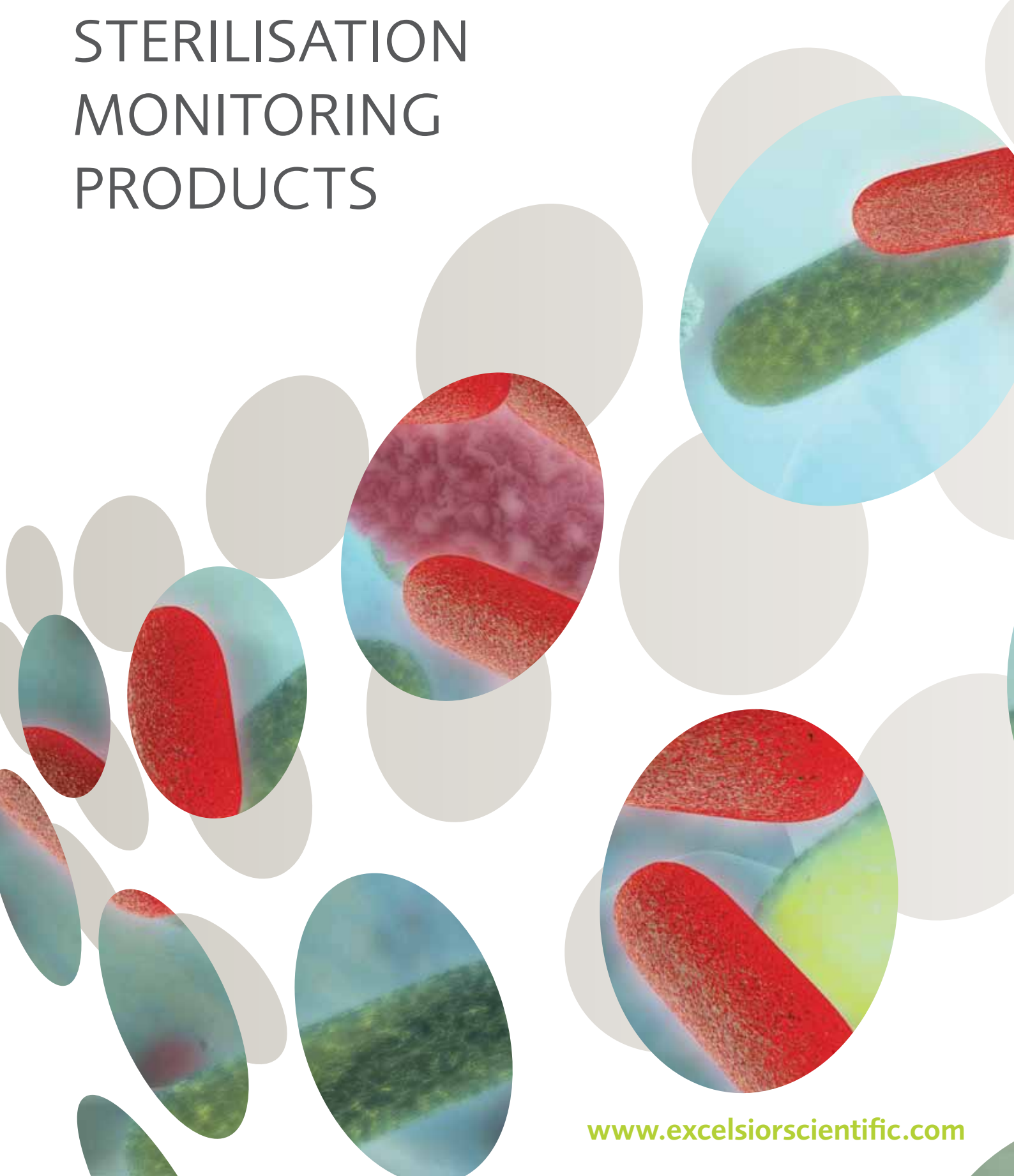




**Excelsior  
Scientific**

# 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.

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**Excelsior  
Scientific**

For additional product information, please call us on **+44 (0) 7813762926**, visit us at **[www.excelsiorscientific.com](http://www.excelsiorscientific.com)** or e-mail us at **[sales@excelsiorscientific.com](mailto:sales@excelsiorscientific.com)**

Excelsior Scientific Ltd.  
United Kingdom

# BOWIE & DICK TESTS

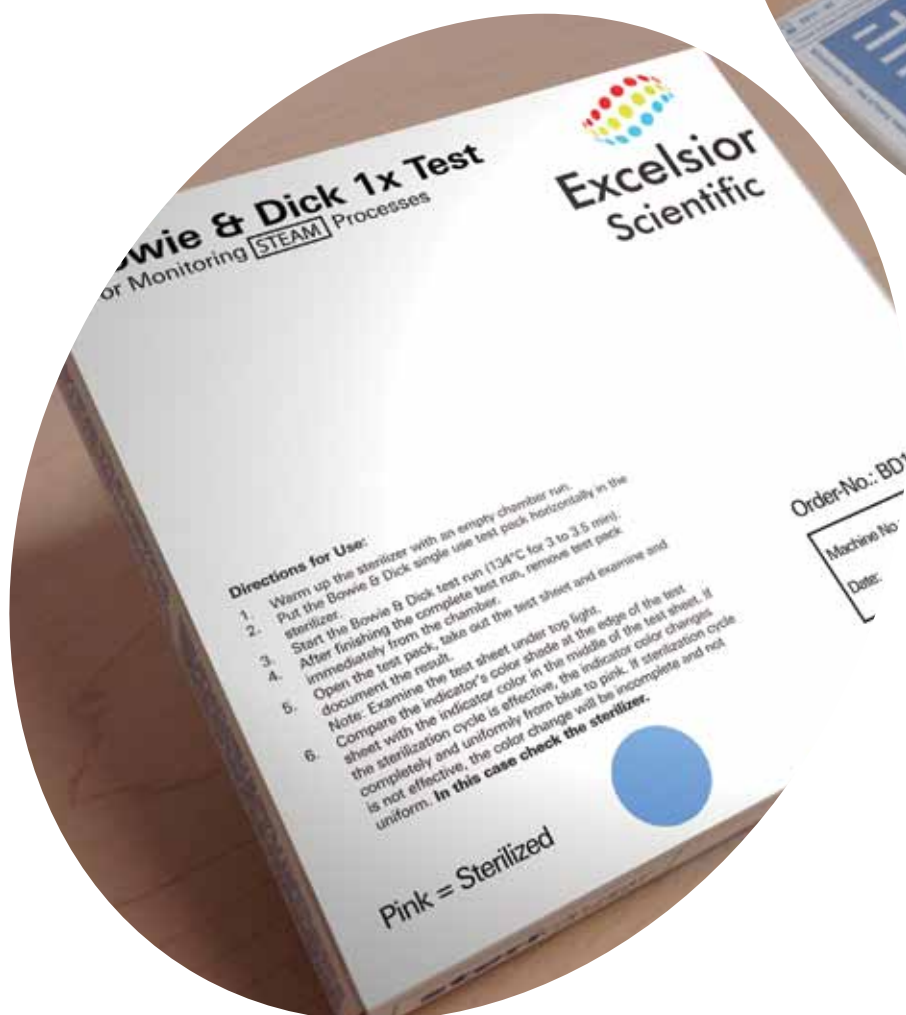
Excelsior offers Bowie & Dick Test packs for monitoring steam sterilisation processes using autoclaves. The Bowie Dick Test Pack consists of a series of steam penetration (air removal) barriers, in the centre of which is a chemical indicator sheet. The test pack should be placed into an empty autoclave 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 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 – 3.5 minutes. 20 Test Packs/Case.
BD-1XE	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) AND MINI SELF-CONTAINED BIOLOGICAL INDICATORS (MSCBI)

Excelsior offers Self-Contained Biological Indicators (SCBI), Mini Self-Contained Biological Indicators (MSCBI) & Rapid Readout Self-Contained Biological Indicator (RSCBI) 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 & RSCBI unit consists of a plastic vial with a cap, a crushable glass ampoule with recovery media, and a disc inoculated with spores. SCBIs, MSCBIs and RSCBIs 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 & MSCBIs also offer a shortened incubation period by comparison (24-48 hours rather than 7 days), with RSCBIs offering the fastest incubation at 9 hours.

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, MSCBIs & RSCBIs 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 ( $15^{\circ}\text{C}$  -  $30^{\circ}\text{C}$ ) conditions. SCBIs which are 12mm x 61mm are offered in boxes of 50 units. MSCBIs & RSCBIs which are 9mm x 50mm are offered in boxes of 100 units. Each box is accompanied by a Certificate of Analysis and Instructions for Use. Excelsior SCBIs are compliant with FDA 510(k): K113302, ANSI/ AAMI/ISO/EN 11138-1 and USP where applicable.



## 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
SCH-06E	Hydrogen Peroxide	Geobacillus stearothermophilus	$10^6$	24 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

## Rapid Readout Self-Contained Biological Indicators

Code	Sterilisation Process	Organism	Pop.	Min. Incubation Period
RSCS-05E	Steam	Geobacillus stearothermophilus	$10^5$	9 hours
RSCS-06E	Steam	Geobacillus stearothermophilus	$10^6$	9 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* 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 ( $5 \pm 3^{\circ}\text{C}$ ). 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
SA1-15-05E	$10^5$	1 mL	15/box
SA1-50-05E	$10^5$	1 mL	50/box
SA1-15-06E	$10^6$	1 mL	15/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  $70^{\circ}\text{C}$  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 $70^{\circ}\text{C}$
INC-13EE	Incubator, European plug type. Ambient to $70^{\circ}\text{C}$
INC-13UE	Incubator, UK plug type. Ambient to $70^{\circ}\text{C}$



# SPORE STRIPS

Excelsior offers a full line of spore strips for use in monitoring sterilisation 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 labelled with a 15 to 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)

## 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 (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 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 10<sup>6</sup>, please enquire.

## Mini Spore Strips - Steam

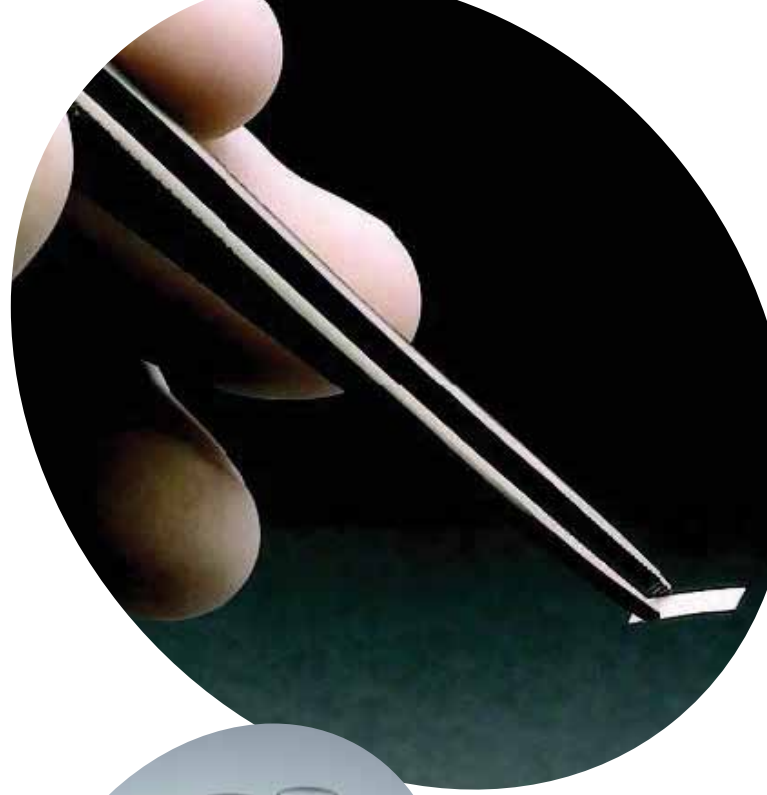
*Geobacillus stearothermophilus* 24 month shelf-life

Code	Packaging	Population
STS-062E	glassine envelopes	10 <sup>6</sup>
STS-062BE	bulk	10 <sup>6</sup>
STS-062MGE	mini-glassine envelopes	10 <sup>6</sup>

## Mini Spore Strips - Ethylene Oxide or Dry Heat

*Bacillus atrophaeus* 24 month shelf-life

Code	Packaging	Population
STN-062E	glassine envelopes	10 <sup>6</sup>
STN-062BE	bulk	10 <sup>6</sup>
STN-062MGE	mini-glassine envelopes	10 <sup>6</sup>



# 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, VH202 & ClO<sub>2</sub> & 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. 510(k) documentation available upon request. Supplied in 16 mm x 100 mm Type I borosilicate glass flat bottom tubes with screw-caps. 100 x 4mL tubes per box.

Code	Sterilisation Process	Organism	Incubation Time
GMBCP-100E	Steam, VH202 or ClO <sub>2</sub>	<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	25 mm	Cotton thread	10 <sup>6</sup> (1,000,000)	Bulk

## Spore Threads - Steam

*Geobacillus stearothermophilus* 12 month shelf-life

Code	Length	Carrier Type	Spore Population Per Strip	Packaging
THS-05E	25 mm	Cotton thread	10 <sup>5</sup> (100,000)	Bulk
THS-06E	25 mm	Cotton thread	10 <sup>6</sup> (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	40 mm	Braided steel	10 <sup>6</sup> (1,000,000)	Bulk

## Spore Wires - Steam

*Geobacillus stearothermophilus* 12 month shelf-life

Code	Length	Carrier Type	Spore Population Per Strip	Packaging
SWS-06E	40 mm	Braided steel	10 <sup>6</sup> (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	40 mm	Braided steel	10 <sup>6</sup> (1,000,000)	Bulk

## Spore Coupons - Hydrogen Peroxide

*Bacillus atrophaeus* 12 month shelf-life

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

## 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	Tyvek®	10 <sup>6</sup> (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 30 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, Zvalue, 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 <sup>6</sup> (1,000,000)	Bulk
DN18-06E	3 mm	Filter paper	10 <sup>6</sup> (1,000,000)	Bulk

## Spore Discs - Steam

*Geobacillus stearothermophilus* 30 month shelf-life

Code	Length	Carrier Type	Spore Population Per Strip	Packaging
DS-06E	6 mm	Filter paper	10 <sup>6</sup> (1,000,000)	Bulk
DS18-06E	3 mm	Filter paper	10 <sup>6</sup> (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 <sup>6</sup> (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 <sup>6</sup> (1,000,000)	Tyvek® / Mylar®
TTS-06E	6 mm	Steel	10 <sup>6</sup> (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 0.1 mL.

Spore Suspensions manufactured with WFI and ethanol or 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 ( $2^{\circ}$  -  $8^{\circ}$ 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, 18 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, 15 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, 14 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 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<sup>6</sup> /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.

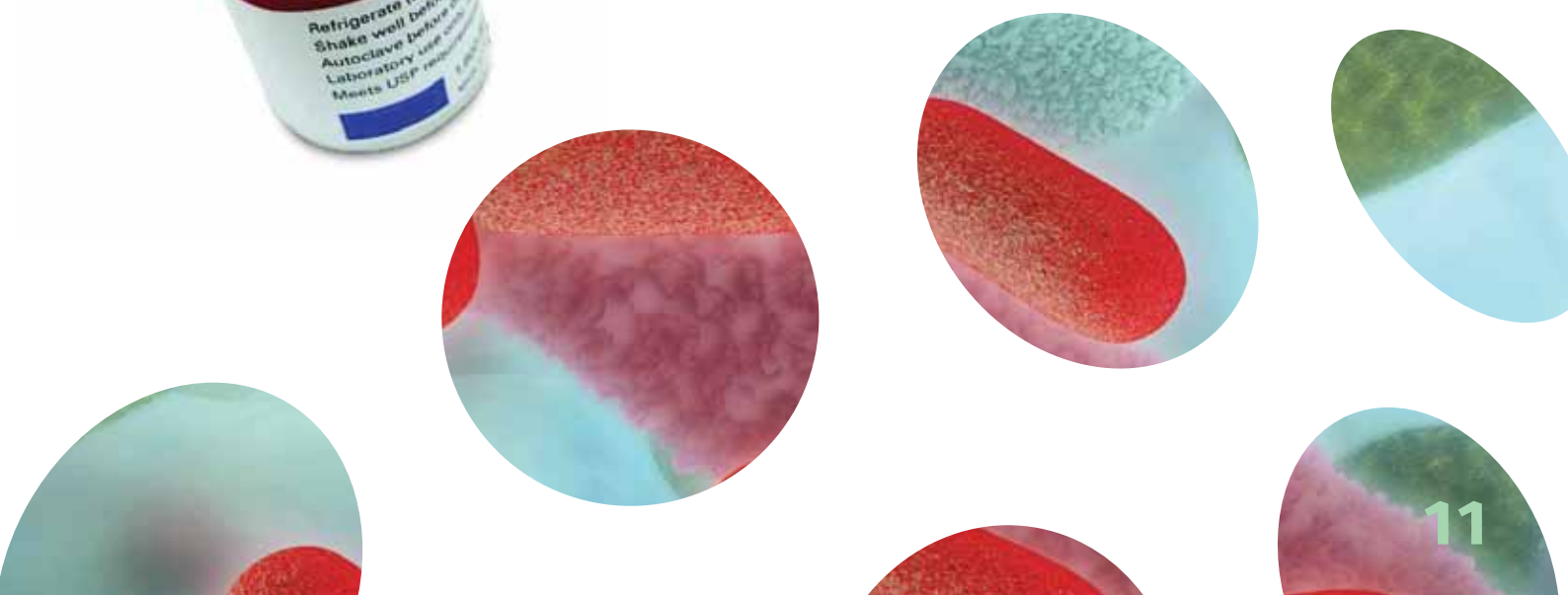
## Growth Promotion Test Suspensions

Code 10ml	Code 2.5ml	Organism	Shelf Life
GP-01E	N/A	Bacillus subtilis (cell line 6633)	14 months
GP-02E	N/A	Clostridium Sporogenes (cell line 11437)	14 months
N/A	GP25-03E	Candida albicans (cell line 11437)	12 weeks
GP-04E	N/A	Aspergillus brasiliensis <sup>1</sup> (cell line 16404)	7 months
GP-06E	N/A	Geobacillus stearothermophilus (cell line 7953)	24 months
N/A	GP25-07E <sup>2</sup>	Pseudomonas aeruginosa (cell line 9027)	8 weeks
N/A	GP25-08E <sup>2</sup>	Staphylococcus Aureus (cell line 6538)	8 weeks
N/A	GP-25-09E	Escherichia coli (cell line 8739)	10 weeks
GP-10E	N/A	Bacillus atrophaeus (cell line 9372)	18 months
N/A	GP-25-11E <sup>2</sup>	Salmonella enterica (cell line 14028)	12 weeks

<sup>1</sup> Formerly known as *Aspergillus niger*

<sup>2</sup> Considered category B as per UN2814 & UN3373, and require special shipping conditions.

N/A = Configuration not available



# 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.

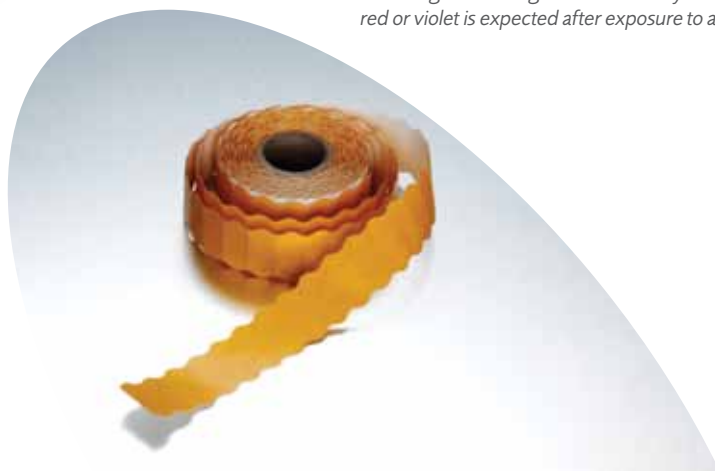
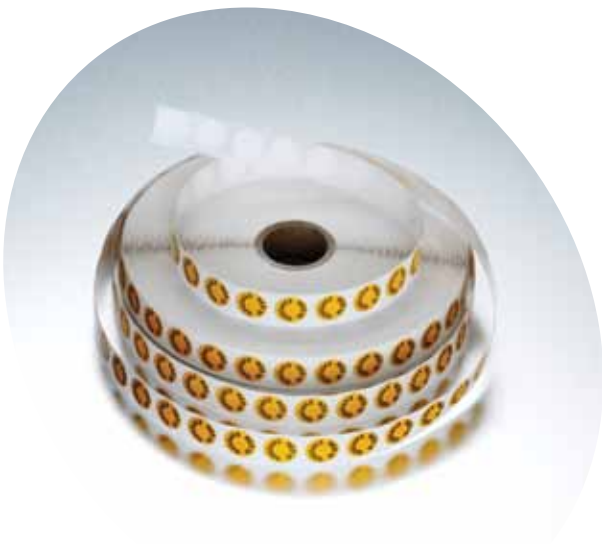


# RADIATION CHEMICAL PROCESS INDICATORS

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  $35^\circ\text{C}$ ) 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 Exposed"	$\geq 10\text{ kGy}$	5,000	
CPI-F01E	Low dose Plain 1/2" (12.7mm)	$\geq 3\text{ kGy}$	5,000	
CPI-R06E	METO® gun indicators for hand-held labelling systems	$\geq 10\text{ kGy}$	1,000	

## Product Colour Change Performance<sup>1</sup> Excelsior Radiation Chemical Process Indicators

Product CPI-R01E			
Unexposed		1 kGy <sup>3</sup>	
UV Light <sup>2</sup> 20 Mins.		10 kGy	

Product CPI-F01E			
Unexposed		1 kGy <sup>3</sup>	
UV Light <sup>2</sup> 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 colour 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

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.

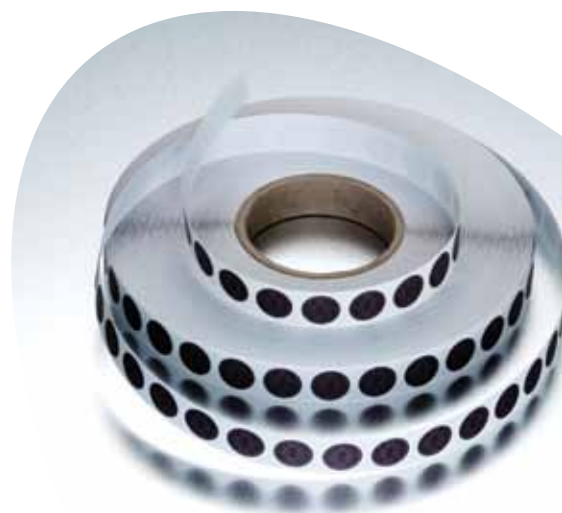
## Process Indicator Configurations

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	
SP-E16E	Imprinted METO® gun indicators for hand-held labelling systems. Text reads: "Green is exposed"	1,500	

## Product Colour Change Performance <sup>1</sup> Excelsior Ethylene Oxide Chemical Process Indicators

Product CPI-E01E			
Unexposed		600 mg/L 54°C 60% RH 2 minutes <sup>3</sup>	
0 mg/L 60°C >85% RH 90 minutes <sup>2</sup>		600 mg/L 54°C 60% RH 2 minutes <sup>4</sup>	

- 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 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.

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-DP1E	Plain 1/2" (12.7mm) circles	$\leq 250^{\circ}\text{C}$	500	
CPI-DH01E	Plain 1/2" (12.7mm) circles	$\leq 180^{\circ}\text{C}$	1,000	

## Product Colour Change Performance <sup>1</sup> Excelsior Depyrogenation Chemical Process Indicators

Product CPI-DP1E			
Unexposed		3 Hours at $180^{\circ}\text{C}$	
30 mins. at $250^{\circ}\text{C}$		1 Hour at $250^{\circ}\text{C}$	

## Product Colour Change Performance Excelsior Dry Heat Chemical Process Indicators

Product CPI-DH01E			
Unexposed		Dry Heat $160^{\circ}\text{C}$ 10 minutes	

<sup>1</sup> 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

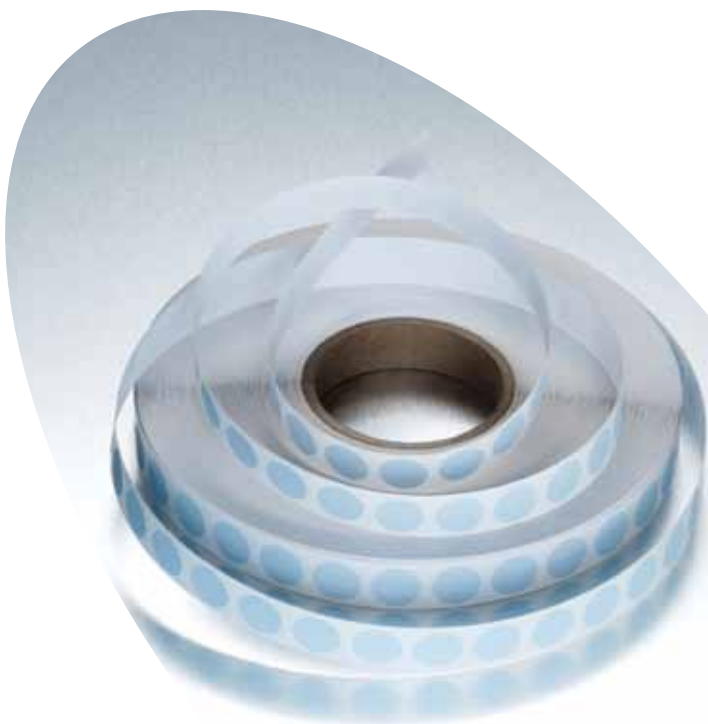
## Process Indicator Configurations

Code	Product Type	Number of CPIs / Roll	Example
CPI-S01E	Plain 1/2" (12.7mm) circles	5,000	
SP-S05E	2.5" x 1.5" label with indicator	1,000	

## Product Colour Change Performance <sup>1</sup> Excelsior Steam Chemical Process Indicators

Product CPI-S01E			
Unexposed		Dry Heat <sup>2</sup> 140°C 30 minutes	
Saturated Steam <sup>3</sup> 121°C - 3 mins.		Saturated Steam 121°C - 3 minutes	
Saturated Steam <sup>4</sup> 121°C - 10 mins.		Saturated Steam <sup>4</sup> 134°C - 2 minutes	

- <sup>1</sup> Samples are representative of performance according to ISO 11140-1, for Class 1 Process Indicators.
- <sup>2</sup> 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.
- <sup>3</sup> After exposure to shortened steam cycles, a change to pink similar to Pantone® 677 C or lighter can be expected.
- <sup>4</sup> 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.

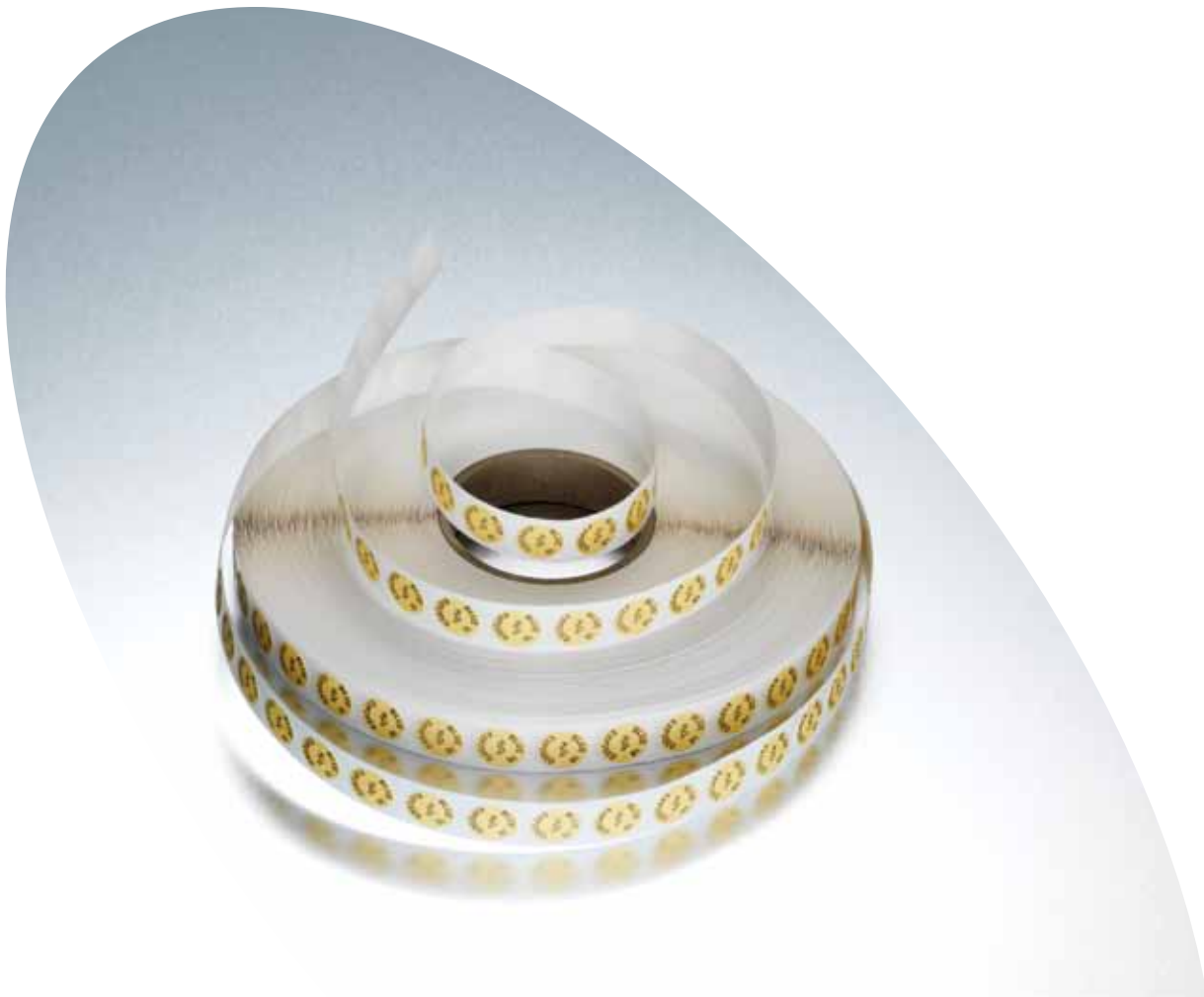
## Process Indicator Configurations

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

## Product Colour Change Performance <sup>1</sup>

### Excelsior Hydrogen peroxide Chemical Process Indicators

Product CPI-P03E			
Unexposed		Exposed 7 seconds at 50°C	
Absence of H <sub>2</sub> O <sub>2</sub> 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.



## Tape Configurations

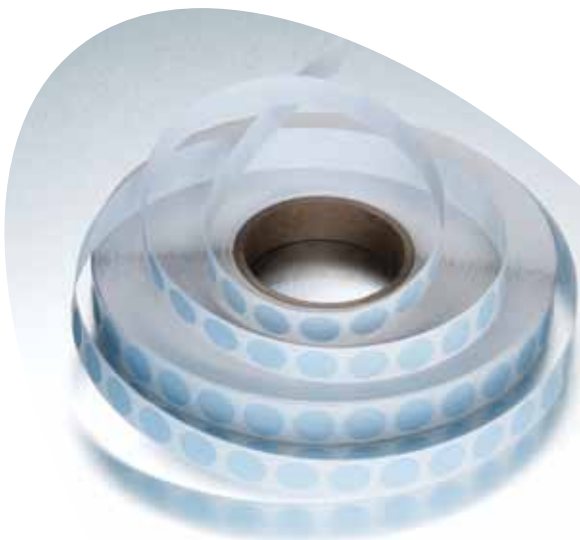
<p>TAP-SCS-E Class 4 Steam Autoclave Tape Irreversible colour transition from Green to Orange. Can be written on 18mm x55m 48 rolls / Box. 24 month shelf life.</p>		
<p>TAP-ECS-E Ethylene Oxide Tape Irreversible colour transition from yellow to dark showing the words: "Dark is Exposed". Can be written on. 18mm x55m 48 rolls / Box. 24 month shelf life.</p>		
<p>TAP-H-E H2o2 Plasma Tape Irreversible colour transition from red to yellow Can be written on. 18mm x55m 48 rolls / Box. 24 month shelf life.</p>		

# 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	Steam	Autoclave TST Strip Class 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 Class 5 integrator. Requires exposure for 3.5 mins at 134°C or 16.5 mins at 121°C. Transitions from yellow to tan. Box of 250.	
TST-6SE	Steam	Autoclave TST Strip Class 6 Emulator. Requires exposure for 3.5 mins at 134°C. Transitions from blue to Pink. Box of 250.	
DH-250E	Dry Heat	Dry Heat Strip. Requires exposure for 40 mins at 160°C or 60mins at 155°C. Transitions from orange to brown. Box of 250.	
HRB-250E	Hydrogen Peroxide	VH2o2 Plasma Strip. Requires 6 mins at 54°C with 2.3 mg/L of vaporised hydrogen peroxide. Transitions from blue to Pink. Box of 250.	
ETO-250E	Ethylene Oxide	E.O Strip. Requires exposure for 20 mins at 55°C at 60% RH using 600 mg/L gas. Transitions from green to blue. Box of 250.	
CH20-250E	Formaldehyde	CH20 Strip. Requires exposure for 15 mins at 70°C. using 1 mol/L of Formaldehyde. Transitions from purple to green. Box of 250.	





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