

Biological Indicators

Self-Contained Biological Indicators (SCBI)

NAMSA offers Self-Contained Biological Indicators (SCBI) for monitoring Ethylene Oxide (EO) sterilization processes in a 10^6 population. Each SCBI unit consists of a plastic vial with a cap, a crushable glass ampule with recovery media, and a paper disc inoculated with spores. SCBIs are ideal for use in sterilization processes where traditional Biological Indicator strips are utilized, however eliminates the need for aseptic transfer of the BI to culture media and offers a shortened incubation period.

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



Self-Contained Biological Indicators

NAMSA Code	Sterilization Process	Organism	Population	Readout
SCE-06	EO	<i>Bacillus atrophaeus</i> ¹	10^6	48 hours

¹ This product may also be used in dry heat sterilization processes with some temperature restriction. Please contact NAMSA for further details.

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

Incubators

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

NAMSA offers a variety of sterilization monitoring products and the full range of pre-clinical safety testing and consulting services to medical device, pharmaceutical and biotech companies throughout the world.

For additional product information:
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