3M™ Attest™ 1264-S Biological Indicator for Ethylene Oxide
3M™ Attest™ Incubators

Product Profile

For Industrial Applications

Industrial Sterilization Specialties
INTERNATIONAL

3M

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Product Description

3M™ Attest™ 1264-S Biological Indicator for Ethylene Oxide

3M Attest 1264-S

The 3M Attest 1264-S Biological Indicator for Ethylene Oxide (EO) is a reliable and convenient biological indicator for validating and monitoring EO sterilization processes. The Attest 1264-S may be used as a component of the quality system for an EO sterilization process that ensures that medical devices are processed per the manufacturer's specifications and comply with therequirements of national and international sterilization standards. The Attest 1264-S should be used with appropriate testing, verification, and documentation by the end user.

The Attest 1264-S is a self-contained biological indicator. This design reduces testing time and eliminates the potential for cross-contamination associated with the culturing of conventional spore strips. The Attest 1264-S design is comprised of a paper carrier inoculated with a standardized population of *Bacillus atrophaeus* ATCC® 9372 spores, a glass ampoule containing recovery medium which includes a pH indicator dye, a plastic cap with filter, and a plastic vial. (See Figure 1) The biological indicator has a chemical process indicator on the label that will change from reddish-brown to green upon exposure to the ethylene oxide sterilization process. The recovery media will produce a pH color change from blue-green to yellow if viable spores are present and incubation conditions are correct.

The Attest 1264-S is verified with a readout or Reduced Incubation Time (RIT) of 48 hours under specific test conditions. 3M recommends that the RIT for Attest 1264-S be validated by the end user in their system.

The Attest 1264-S can be incubated for up to 7 days with specific action to prevent media dry-out. A change in media color from blue-green to yellow indicates a positive biological indicator result.

3M Model 127 Incubator

The Attest 1264-S may be incubated in a 3M Model 127 incubator, or any microbiological incubator providing the appropriate incubation temperature [37°C ± 2°C (99°F ± 2°F)].

The Attest 1264-S has not been tested or validated for monitoring sterilization processes other than ethylene oxide, such as steam, dry heat, radiation, hydrogen peroxide, or other chemical or low temperature processes.

The Attest 1264-S is available in cases containing 2 boxes of 300 BIs (600 BIs per case).

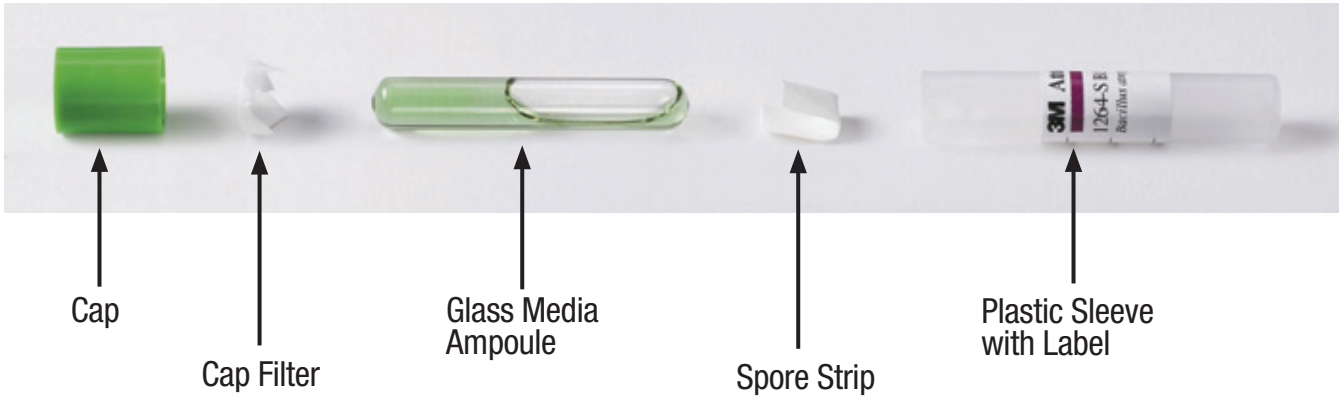

Figure 1 - 3M Attest 1264-S Components

Regulatory Status

The Attest 1264-S is compliant with ISO 11138-1:2006[1] and ISO 11138-2:2006[2] (ANSI/AAMI/ISO 11138-1:2006[3] and ANSI/AAMI/ISO 11138-2:2006[4]). Key product design and performance specifications for the Attest 1264-S are provided in Section III of this Product Profile.

The 3M Attest 1264-S, when used to monitor industrial sterilization processes, is not regulated by the U.S. FDA as a medical device. The 3M Attest 1264-S is equivalent to the 3M Attest 1264 Biological Indicator for Ethylene Oxide, which is a Pre-Amendment Device.

Product Specification and Performance Information

The following sections describe the key performance specifications of the Attest 1264-S system, in some cases comparing them to the biological indicator requirements described in ***ISO 11138-2 (2006) Sterilization of health care products – Biological indicators for ethylene oxide sterilization processes***.

Population Specification	
3M Attest 1264-S	$1.0 \times 10^6 – 9.9 \times 10^6$ cfu/strip
ISO 11138-2:2006 – Ethylene Oxide BIs	1.0×10^6 cfu/strip minimum

Table 1- Population

Method: The method used for determination of viable population of the Attest 1264-S involves maceration of multiple strips to separate the spores from the paper carrier, followed by serial dilutions, plating, colony counting, and dilution calculations to determine the population. Population test results are very dependent upon the methodology used to determine those results. The test method used to confirm the population of any lot of Attest 1264-S must be identical to the method used by 3M to determine the population stated on the certification. The 3M method is described in ***3M Technical Bulletin 05-000003, 3M EO Biological Indicators – Population Test Procedure***, available upon request (In the U.S., all the 3M Sterilization Technical Helpline at 1-800-441-1922, Option 2 or through your local 3M office).

Rationale: The population range for Attest 1264-S is narrower than the population range specified for ethylene oxide biological indicators in ISO 11138-2. The intent of this narrower specification is to provide a less variable indicator.

D-value Specification	
3M Attest 1264-S	2.5 – 4.0 minutes
ISO 11138-2:2006 – Ethylene Oxide BIs	2.5 minutes minimum

Table 2 - D-value

Method: The D-value for Attest 1264-S is determined using a Fraction Negative methodology. All exposures are completed under the following conditions:

600 mg/l ±30 mg/l ethylene oxide
54ºC±1ºC
60% ± 10% RH
Oxyfume® 2002 Gas

The test method used to confirm the D-value of any lot of Attest 1264-S must be identical to the method used by 3M to determine the D-value stated on the certification. The specific 3M method is described in ***3M Technical Bulletin 05-000004, 3M Attest 1264-S D-value Test Method***, available upon request (In the U.S., call the 3M Sterilization Technical Helpline at 800-441-1922, Option 2 or through you local 3M office).

Rationale: The D-value specification for Attest 1264-S is narrower than the range specified in for ethylene oxide biological indicators in ISO 11138-2:2006. The intent of this specification is to provide a less variable indicator.

Survival and Kill

The survival and kill values of the Attest 1264-S are based on the calculations specified in ISO 11138-1:2006. The formulas are:

Survival Time = (log_{10} population – 2) x D-value

Kill Time = (log_{10} population + 4) x D-value

These tests are conducted in an EO resistometer at 600 mg/l ± 30mg/l EO, 54ºC ± 1ºC, 60% ± 10% RH, using Oxyfume® 2002 gas. The actual calculated test times for each lot are reported on the Quality Certificate that accompanies each lot.

Readout (Reduced Incubation) Time

The reference incubation time for biological indicators is generally considered to be seven days (168 hours). Incubation times of less than seven days, i.e., the "readout" or reduced incubation times (RIT) therefore need to be validated by appropriate testing. RIT testing is performed to establish the shortest incubation time necessary to ensure a high degree of confidence for detecting a positive biological indicator response.

Sensitivity is the statistic used to calculate the RIT. With the Attest 1264-S, sensitivity is a measure of the accuracy of the 48 hour readout to indicate spore survival following an EO sterilization process failure or exposure in a sub-lethal cycle, as compared to the indicator response at 168 hours. The minimum incubation time for a reliable readout will have a very small number of false negatives and consequently a very high sensitivity.

$$\text{Sensitivity} = \frac{(\#\text{ Growth Positives after 7 days} - \#\text{ False Negatives}) \times 100}{\#\text{ Growth Positives after 7 days}}$$

Note: A false negative is defined as a biological indicator showing a negative response at 48 hours incubation time and a positive response at 7 days incubation time.

The Attest 1264-S is routinely verified with a reduced incubation time (RIT) of 48 hours under a specific 3M test plan targeting a minimum sensitivity of 95%.

The test plan used by 3M is a sequential attribute-sampling plan designed to have certain operating characteristics that assure the RIT requirements are met on a consistent basis. Each crop of *Bacillus atrophaeus* spores is tested for RIT using this procedure. Generally, a minimum of 400 Attest 1264-S units are tested for each spore crop. While a spore crop produces multiple lots of Attest 1264-S, each individual product lot is traceable to the RIT test data for that pertinent spore crop. The test method limits are set so that there is a 5% probability that a lot which has 95% or better RIT is rejected (producer's risk, i.e., reject a good lot), and a 10% probability of failing to reject a bad lot (defined by the test plan as 90% RIT, i.e., consumer's risk).

The RIT for 1264-S should be validated by the end user in their sterilization and incubation system.

The specific 3M method for verifying the Reduced Incubation Time for Attest 1264-S is described in ***3M Technical Bulletin 05-000016, 3M Attest 1264-S Reduced Incubation Time Verification Procedure***, available upon request (In the U.S., call the 3M Sterilization Technical Helpline at 800-441-1922, Option 2 or through your local 3M office).

Instructions for Use

The following information is provided with the Attest 1264-S biological indicators and provides specific use instructions.

Identification and Expiration Date: Each biological indicator will be labeled with a lot code that also provides the expiration date information. The format of this code is noted below:

YYYY-MM XX

Y denotes the Year the product will expire;
M denotes the Month the product will expire (last day of that month); "XX" is a 3M lot specific code. For example:

2010-03 JK

represents a product with production code JK that will expire on March 31, 2010.

The entire lot code (8 characters) must be used to describe or document the product lot. Biological indicators that are beyond their expiration date should not be used.

Inspection: Damaged biological indicators may produce erroneous results. Indicators can be damaged in shipping, or in handling (e.g. during placement into, or extraction from, product or PCDs; damage by pallet handling before or after processing). Careful inspection of the biological indicator both before and after processing (before crushing the ampoule) is critical. (Note: Please follow safety precautions described in WARNING section when inspecting indicators that have been exposed to the sterilization process).

Carefully inspect each biological indicator for:

Missing or damaged components (e.g. cap filter, spore strip, media ampoule, plastic sleeve).

The integrity of the glass ampoule is critical. Inspect for any signs of breakage including wet spore strip, yellow media, wet or dried residual media inside vial, or apparent lack of media in the ampoule.

Any damaged or suspect biological indicators should be discarded. Any results obtained from damaged biological indicators should be considered suspect.

Positive Control Tests: Positive controls (unprocessed indicators) should be tested to ensure that storage or handling has not inadvertently affected the viability of the indicator organisms or the ability of the recovery media to promote bacterial growth. Positive controls also verify that incubation conditions are appropriate.

Test at least one positive control from the same biological indicator lot for each sterilizer load monitored. Verify that the color of the chemical indicator on the biological indicator label is reddish-brown (unprocessed color). To test the positive controls, crack the glass ampoule (note WARNING section below) and ensure that the growth media completely wets the spore strip. Incubate the positive controls at 37ºC ± 2ºC (99ºF ± 3ºF) with the processed indicators, for up to 48 hours. The media color must change from blue-green to yellow (yellow indicates a positive biological indicator) within 48 hours. Do not continue to incubate indicators that have turned positive. Failure of the positive control test may invalidate the processed indicator results.

Product Handling Information

Storage: Store Attest 1264-S biological indicators between 15-30ºC (59-86ºF) and 35% - 60% relative humidity (RH). Do not store near sterilants or other chemicals.

Disposal: Dispose of biological indicators per your facility procedure. You may wish to autoclave biological indicators at 121ºC/250ºF for at least 30 minutes.

References

1. *Sterilization of health care products --- Biological indicators – Part 1: General requirements*. International Organization for Standardization; 2006. ISO 11138-1.

2. *Sterilization of health care products --- Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes*. International Organization for Standardization; 2006. ISO 11138-2.

3. *Sterilization of health care products --- Biological indicators – Part 1: General requirements*. Association for the Advancement of Medical Instrumentation; 2006. ANSI/AAMI/ISO 11138-1.

4. *Sterilization of health care products --- Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes*. Association for the Advancement of Medical Instrumentation; 2006. ANSI/AAMI/ISO 11138-2.

Call us at Customer Service to place an order: 800-742-1994 (U.S.). Visit our website: **www.3M.com/medicalspecialties** for product and services information, news about conferences we will be attending, new product highlights or to make a direct inquiry

To have a sales representative contact you, or to request samples, please contact us at 3M HELPLINE 800-228-3957 (U.S.) or for international inquiries, please contact your local country representative. Our 3M Medical Specialties subsidiary contacts are listed below.

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