

# Envomed 80 Biological and Chemical Indicator Kits

Guarantee your Regulated Medical Waste  
Treatment System Integrity



# Compliance Made Easy

The Envomed 80 can treat 80 liters of infectious and sharps medical waste in just 15 minutes – sterilizing to STAATT Level IV – our test kits will help you confirm it.

At Envomed, we understand the importance of complying with sterilization regulations – it’s what we do every day. We have developed two tools designed to allow you to guarantee the effectiveness of your Envomed 80’s sterilization process and to comply with the STAATT recommendations. Using these testing kits routinely will give you peace of mind, by providing empirical evidence of your RMW (Regulated Medical Waste) system integrity and that your sterilization efficacy target is met.

## Sterilization, Disinfection and STAATT Guidelines

Process	Definition	Inactivation Level	STAATT Level
Disinfection	Demonstrates a reduction of most pathogenic organisms from a system	Disinfection demonstrates a 4 log <sub>10</sub> reduction of bacterial endospores and 6 log <sub>10</sub> reduction of vegetative bacterial cells	Level III
Sterilization	Demonstrates the complete elimination of all pathogenic microorganisms’ forms, including bacterial endospores.	Sterilization demonstrates a 6 log <sub>10</sub> reduction of bacterial endospores and 6 log <sub>10</sub> reduction of vegetative bacterial cells	Level IV

### What is a Biological Indicator?



A biological indicator is a non-pathogenic microorganism used to test the sterilization processes. Envomed’s testing kits use *Geobacillus Stearothermophilus* ATCC 7953 as a biological indicator to represent the presence or absence of other microorganisms after sterilization. This microorganism is an endospore forming bacteria, and therefore is the most challenging in the sterilization process.

### What is a Bacterial Endospore?



A bacterial endospore is a dormant, firm, non-reproductive and non-metabolically active structure produced by some of the Phylum Firmicutes bacterial families. A bacterial endospore can survive extreme environmental conditions that would in any other circumstance eliminate the vegetative bacterium. It is therefore the perfect candidate to test the efficacy of sterilization processes.

# The Biological Performance Verification Kit Process

Routine monitoring of your sterilization process is of critical importance. Envomed's specially designed Performance Verification Biological Kits make the testing process easier, and provide an actual demonstration of spore elimination based on PAA sporicidal activity. We recommend users of the Envomed 80 perform the verification testing process at least once a month, in line with STAATT guidelines.

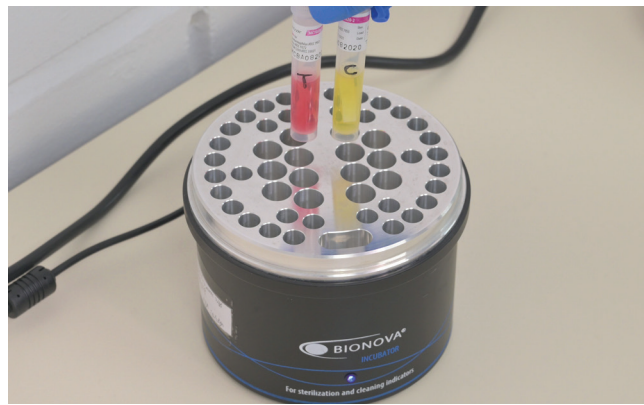
## Disinfection Performance Verification by Biological Kit



Envomed's biological performance verification kit provides empirical, biological evidence of the efficacy of your sterilization process, including the combined parameters of PAA concentration, temperature and duration. As a form of biological qualitative challenge testing, our procedure means you will be able to accurately verify the growth / no growth of spores following treatment results. The kit includes two main steps:



**1** The treatment of the spores envelope in the Envomed 80 unit.



**2** A laboratory step requiring the spores strip to be incubated for 24 hours. The above indicates a 'passed' test.



The "Envomed 80 – Performance Verification Procedure" instructional Video is available on the Envomed website:

<https://envomed.com/category/videos>

## Quick and Clear Results Verification

Envomed has designed an easy-to-use color coded verification method so you can quickly interpret the results of your testing.

In order for the results to be valid, the Growth Medium used for incubating spores' strips which have not been disinfected (positive control) should turn yellow (See image above).

If after 24 hours no color change is visible on the growth medium tube containing the treated strip (Test), the disinfection process was successful, meaning the result is negative. Any failure in the disinfection process will be clearly indicated by the growth medium indicator turning yellow.

# Biocetic Integrity Verification



It's also critically important to routinely test the concentration of your Biocetic solution, along with the Envomed 80 dosage pump accuracy and embedded water heater.

Envomed recommends that you test this on a weekly basis, or any time a new Biocetic batch is used.

This form of testing allows you to establish the efficacy of your disinfection process when integration conditions reach established parameters - temperature (°C), duration (min) and PAA concentration (ppm).

The test is designed to verify that the Biocetic solution contains an adequate concentration of the active substance Peracetic Acid, in combination with the process temperature and exposure duration.

Giving you complete peace of mind, the test will return an "Optimal" result if the entire complex of parameters complied with your process definition.



For instructions on how to carry out the testing process, please refer to the "Envomed 80 – Performance Verification Procedure" Video on the Envomed website:

<https://envomed.com/category/videos>

## Order your Performance Verification Test Kits today!



To carry out both performance verification tests, the following utensils are required. All of which may be purchased directly from your distributor. For more information, contact us at [www.envomed.com](http://www.envomed.com)

Process	Code	Kit	Contents
Biological performance verification	ENVKBT 400	Spore Culture Medium+Spore strips 100 pcs per pack	The kit contains: <ul style="list-style-type: none"><li>• 100 non-absorbent material envelope. Within the envelope, there is polyethylene fiber strip containing <math>10^6</math> <i>Geobacillus Stearothermophilus</i> ATCC 7953 spores per strip.</li><li>• 100 units, 2ml tubes of a color changing indicative culture medium specially designed for <i>Geobacillus Stearothermophilus</i> culture.</li></ul>
	IC10/20	Dual Biological indicator Incubator	Incubator includes a heating block with 10 positions for culture medium. The incubator is pre-set to $60\pm2^\circ\text{C}$ .
Biocetic integrity, performance verification	ENV-401PAA	Peracetic Acid Chemical Indicator 100 pcs per pack	This chemical indicator kit contains 100 non-absorbent material envelope. Within the envelope, there is an indicator strip, printed with a color changing reactive ink specific for PAA reaction.