

## 05290 Sterility Indicator (Radiation Sterilization)

These indicators consist of *Bacillus pumilus* (ATCC 27142) spores impregnated on paper strips, individually placed into envelopes. Number of spores present per strip: 1 million. *Bacillus pumilus* is a radiation resistance species. The spores are highly resistant and are used to monitor efficiency of radiation sterilization. These indicators as specified by U.S. military specification MIL-S-36586 are GMP requirements of U.S. FDA.

### Composition:

(1 package contains 25 test strips)

One paper strip is impregnated with 1 million spores from *Bacillus pumilus* (ATCC 27142)

### Directions:

Place indicators so that they are exposed to the radiation as the media and the equipment. For the routine evaluation of each radiated lot a standard procedure should be established. After radiation sterilization using rigid aseptic techniques and open the envelope with the strip inside.

Inoculate strip in a tube with sterile CASO Broth (Fluka 22098) and incubate at 35-37°C up to 7 days.

Simultaneously an unexposed spore strip is inoculated separately in another tube with sterile CASO Broth.

### Quality control:

Cultural response observed after 7 days at 35°C in CASO Broth (Fluka 22098):

Spore Strip	Result
Exposed to radiation	no growth
Unexposed	luxuriant growth