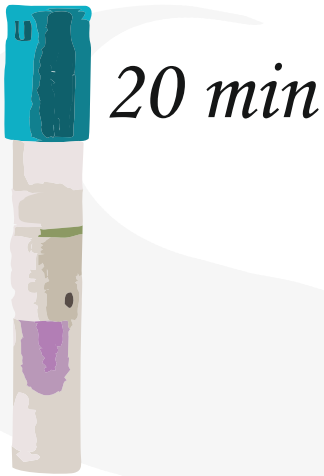
Data Sheet

Biological Indicators

SVSBI20M

Super Rapid Readout System

For Steam Sterilization



Biological Indicators
For Steam Sterilization

SVSBI20M

Product Description

SVSBI20M Super Steam Rapid Readout biological indicators for steam sterilization processes have been designed for the fast and easy monitoring of vacuum assisted and gravity displacement steam sterilization cycles at 121°C-134°C. They consist of plastic tube, a special filter; a spores carrier and a glass ampoule with the culture medium. The tube has a plastic top with three holes and a barrier permeable to steam.

Recommended use

Sterilization process indicator, To indicate attainment of conditions for sterilization.

Specifications

If sterilization process was not successful, the purple culture media will change to a greenish gray and then to yellow, after incubation at 60±2°C, thus showing the presence of live *Geobacillus stearotermophilus* ATTC 7953 spores. If the sterilization process is successful, the culture medium will remain purple after incubation process. The final negative result is obtained after 20 minute of incubation.

Applicable standards

ISO 13485
ISO 9001
ISO 11138-1 Sterilization of health care products – Biological indicators – Part 1: General requirements
ISO 11138-3 Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes

Important

You should use SVSBI20M Super Rapid Steam biological indicators for only monitoring steam sterilization.

Storage

Store it in a dark place and temperatures between
-15-30ºC,
-35-60 % relative humidity.
Do not freeze.
Do not store these biological indicator near sterilizing agents or other chemical products.

Shelf Life

24 month. Available on box.

Important

A color change to yellow of the growth indicator media means a sterilization process failure has occurred. If within 1 hours there is no color change in the processed indicators, a final negative result is made (the sterilization process was acceptable).

Disposal

Discard biological indicators after use according to your country's healthcare and safety regulations. The positive biological indicator can be autoclaved at 121 ºC for at least 20 minutes, or at 132 ºC for 15 minutes in a gravity displacement steam sterilizer, or at 134 ºC for 10 minutes in a vacuum assisted steam sterilizer.

Manufacturer: BF MEDİKAL SANAYİ İTHALAT İHRACAT TİCARET LTD.ŞTİ.
Feridun Çelik Mah. 1743. Sok. No:6/B
Altındağ Ankara/TURKEY 06360
export@sterivision.com.tr

SteriVision
STERILIZATION PRODUCTS

Data Sheet

Biological Indicators

SVSBI3H

For Steam Sterilization

rapid readout 3 hour saat

Biological Indicators

For Steam sterilization

SVSBI3H

Product Description

SVSBI3H Steam Rapid Readout biological indicators for steam sterilization processes have been designed for the fast and easy monitoring of vacuum assisted and gravity displacement steam sterilization cycles at 121°C-134°C. They consist of plastic tube, a special filter; a spores carrier and a glass ampoule with the culture medium. The tube has a plastic top with three holes and a barrier permeable to steam.

Recommended use

Sterilization process indicator, to indicate attainment of conditions for sterilization.

Specifications

If sterilization process was not successful, the purple culture media will change to a greenish gray and then to yellow, after incubation at 60±2°C, thus showing the presence of live *Geobacillus stearothermophilus* ATTC 7953 spores. If sterilization process has not been successful, culture medium will change to a to yellow during incubation at 60ºC, thus showing the presence of living spores (positive result). If sterilization process is successful culture medium will remain purple after the incubation process (negative result).

Applicable standards

ISO 13485
ISO 9001
ISO 11138-1 Sterilization of health care products – Biological indicators – Part 1: General requirements
ISO 11138-3 Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes

Important

You should use SVSBI3H Rapid Steam biological indicators for only monitoring steam sterilization.

Storage

Store it in a dark place and temperatures between
-15-30ºC,
-35-60 % relative humidity.
Do not freeze.
Do not store these biological indicator near sterilizing agents or other chemical products.

Shelf Life

24 month. Available on box.

Important

A color change to yellow of the growth indicator media means a sterilization process failure has occurred. If within 3 hours there is no color change in the processed indicators, a final negative result is made (the sterilization process was acceptable).

Disposal

Discard biological indicators after use according to your country's healthcare and safety regulations. The positive biological indicator can be autoclaved at 121ºC for at least 20 minutes, or at 132ºC for 15 minutes in a gravity displacement steam sterilizer, or at 134ºC for 10 minutes in a vacuum assisted steam sterilizer.

Manufacturer: BF MEDİKAL SANAYİ İTHALAT İHRACAT TİCARET LTD.ŞTİ.

Feridun Çelik Mah. 1743. Sok. No:6/B

Altındağ Ankara/TURKEY 06360

export@sterivision.com.tr

SteriVision
STERILIZATION PRODUCTS

Data Sheet

Biological Indicators

SVSBI24H

For Steam Sterilization

24 *hour*
saat

Biological Indicators
For Steam sterilization

SVSBI24H

Product Description

SVSBI24H Steam biological indicators for steam sterilization processes have been designed for the easy monitoring of vacuum assisted and gravity displacement steam sterilization cycles at 121°C-134°C. They consist of plastic tube, a special filter; a spores carrier and a glass ampoule with the culture medium.

Recommended use

Sterilization process indicator, to indicate attainment of conditions for sterilization.

Specifications

If sterilization process was not successful, the purple culture media will change to a greenish gray and then to yellow, after incubation at 60±2°C, thus showing the presence of live *Geobacillus stearotermophilus* ATTC 7953 spores. If sterilization process has not been successful, culture medium will change to a to yellow during incubation at 60ºC, thus showing the presence of living spores (positive result). If sterilization process is successful culture medium will remain purple after the incubation process (negative result).

Applicable standards

ISO 13485
ISO 9001
ISO 11138-1 Sterilization of health care products – Biological indicators – Part 1: General requirements
ISO 11138-3 Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes

Important

You should use **SVSBI24H** Steam biological indicators for only monitoring steam sterilization.

Storage

Store it in a dark place and temperatures between
-15-30ºC,
-35-60 % relative humidity.
Do not freeze.
Do not store these biological indicator near sterilizing agents or other chemical products.

Shelf Life

24 month. Available on box.

Important

A color change to yellow of the growth indicator media means a sterilization process failure has occurred. If within 24 hours there is no color change in the processed indicators, a final negative result is made (the sterilization process was acceptable).

Disposal

Discard biological indicators after use according to your country's healthcare and safety regulations. The positive biological indicator can be autoclaved at 121ºC for at least 20 minutes, or at 132ºC for 15 minutes in a gravity displacement steam sterilizer, or at 134ºC for 10 minutes in a vacuum assisted steam sterilizer.

Manufacturer: BF MEDİKAL SANAYİ İTHALAT İHRACAT TİCARET LTD.ŞTİ.
Feridun Çelik Mah. 1743. Sok. No:6/B
Altındağ Ankara/TURKEY 06360
export@sterivision.com.tr

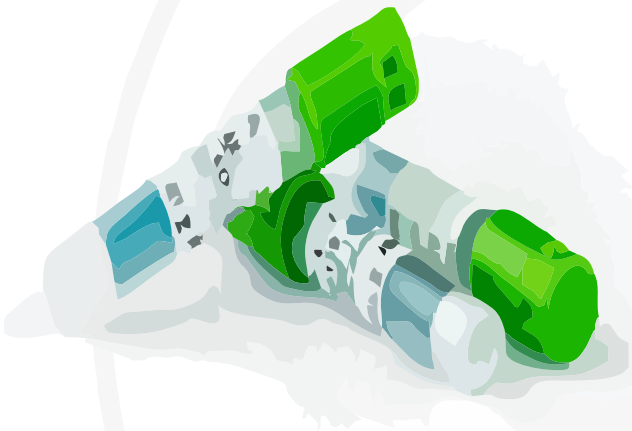
SteriVision
STERILIZATION PRODUCTS

Ethylene Oxide | **RAPID BIOLOGICAL INDICATOR**

EN

SVEOBI4H

Self-contained Biological Indicator.
Rapid Readout Fluorescence System.



Usage

This indicator used for Monitor Ethylene Oxide Sterilization Processes.

Applicable Regulation

ISO 11138-1:2006 and ISO 11138-2:2006; IRAM 37102-1:1999 and IRAM 37102-2:1999.

Classification

Class 1, according to risk.

Authorization

Designed under Quality Management System standards ISO 13485:2003/NS-EN ISO 13485:2012. ANMAT (Argentinean National Administration of Drugs, Food and Medical Technology) PM 1614-1.

Measurement System

Fluorescent Glow, 4 Hour

Characteristics

Polypropylene random copolymer tube: 50.0 mm high x 8.5 mm external diameter. Wall thickness: 0.5 mm
Polypropylene microfiber cap at the bottom of the tube.
Polypropylene cap: 10.5 mm external diameter, 16.5 mm high. Wall thickness: 1.0 mm
Glass ampoule: 35.0 – 38.0 mm high. mm. External diameter: 6.5 mm. Wall thickness: 0.2 – 0.3 mm.
Culture medium 0.5 – 0.7 ml, blue color.
Cap filter: medical grade pape, 60 g/m2
, 16.0 mm diameter.
Filter Paper: 5.0 x 20.0 mm, 160 g/m2 ≥ 10^6 Bacillus atrophaeus ATCC 9372 spores per vial.
Final fluorescence reading: at 4 hour-incubation at 37 ºC (sensitivity:97%). An optional visual pH color change confirmation could be made after 48 hours of incubation. If sterilization process has not been successful, culture medium will change to a greenish color first, and then to yellow during incubation at 37 ºC, thus showing the presence of living spores. If sterilization process is successful culture medium will remain blue after the incubation process.
7-day readout for visual confirmation by color change is optional and not intended to be routinely performed; it is an initial validation of the 4 hour-reading. Fluorescence results may be compared to the 7-day visual reading. If sterilization process has not been successful, culture medium will change to a greenish color and then to yellow during incubation at 37 ºC, thus showing the presence of living spores.
If sterilization process is successful culture medium will remain blue after the incubation process.
NOTE: if 7-day readout is performed, a humidified environment will be required to avoid medium dry out.
D-Value: Not lower than 2.5 minutes, conditions: 600 ± 30 mg/l EO, 60 ± 10 % RH, 54 ± 1 ºC.

SteriVision
STERILIZATION PRODUCTS

Ethylene Oxide | **RAPID BIOLOGICAL INDICATOR**

EN

Environmental conditions during manufacture
Room temperature 15-30 ºC, RH 30-80 %. Sterility conditions are necessary only during the inoculation process performed in laminar flow.

Storage conditions
Under next condition: T = 10-30 ºC, RH 30-80 % In the original box to the best stored

Shelf-life
24 months.

Transportation conditions
Storage conditions should be strictly followed.
Products should be transported in closed and reinforced boxes in order to avoid damages. Product transportation does not represent any risk for human health.

Labelling
On product: 17.0 mm x 33.0 mm polypropylene label. Printed in black. 1.5 mm chemical indicator line, printed with EO reactive ink (Color change to green).
Product code and batch number, process for intended use and bacterial strain.
On product's box: product code, batch number, bacterial load, manufacture and expiration date.

Packing
50 units per box.
Packing information: Product code and description, process for intended use, presentation, classification according to regulation, manufacturer information and data on box´s label. Note: manufacture date is calculated by subtracting 24 months to the expiration date.
Weight per box: 143,8 g.

Possible target markets
Healthcare and Industries.

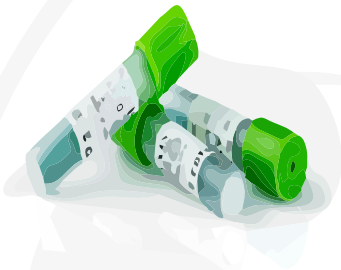
Precautions
Do not store the product near sterilizing agents.
Do not expose this product to Steam, Dry Heat, Radiation or any sterilization process other than EO.
The positive biological indicator can be autoclaved at 121 ºC for at least 20 minutes, at 132 ºC for at least 15 minutes in gravity displacement steam sterilization, or at 134 ºC for at least 10 minutes in vacuum steam sterilizer.

Manufacturer: BF MEDİKAL SANAYİ İTHALAT İHRACAT TİCARET LTD.ŞTİ.
Feridun Çelik Mah. 1743. Sok. No:6/B
Altındağ Ankara/TURKEY 06360
export@sterivision.com.tr

SteriVision
STERILIZATION PRODUCTS

SVEOBI48H

EO Biological Indicator (48h.)
EO Sterilization Control Product



Usage
Ethylene oxide gas is used to monitor sterilization processes.

Applicable Regulation
13485:2016/NS-EN ISO 13485:2016.
ISO 11140-1:2014 and ISO 11140-3:2007

Classification
Class 1, according to risk.

Authorization
Designed under Quality Management System standards ISO 13485:2003/NS-EN ISO 13485:2012. ANMAT (Argentinean National Administration of Drugs, Food and Medical Technology) PM 1614-1.

Measurement System
Colorimetric, 48 Hours

Characteristics
Polypropylene random copolymer tube:
45.0 mm high x 8.5 mm
external diameter. Wall thickness: 0.5 mm.
Polypropylene cap:
13.0 mm high, 10.5 mm external diameter. Wall thickness: 1.0 mm.
Glass ampoule:
35.0 – 38.0 mm high. External diameter: 6.5 mm. Wall thickness: 0.2 – 0.3 mm.
Culture medium:
0.5 – 0.7 ml, blue color.
Cap filter:
medical grade paper, 60 g/m2, 16.0 mm diameter.
Filter Paper: 8.0 mm diameter, 160 g/m2
Bacillus atrophaeus ATCC 9372 spores per vial.
Positive growth results (failure in the sterilization process):
Culture medium turns to yellow, incubation at 37 ºC for 48 hours (maximum).
D-Value: Not lower than 2.5 minutes, conditions: 600 ± 30 mg/l EO, 60 ±10 % RH, 54 ± 1 ºC.

Environmental conditions during manufacture
Room temperature 15-30 ºC, RH 30-80 %. Sterility conditions are necessary only during the inoculation process performed in laminar flow.

Storage conditions
T = 10-30 ºC, RH = 30-80 %, keep out of direct light.

Transportation conditions
Storage conditions should be strictly followed.
Products should be transported in closed and reinforced boxes in order to avoid damages. Product transportation does not represent any risk for human health.

Ethylene Oxide | **BIOLOGICAL INDICATOR**

EN

Shelf-life
24 months.

Packing
100 units per box.
Packing information: product code and description, presentation, process for intended use, classification according to regulation, manufacturer information and data on label.

Labelling
On product: 17.0 mm x 33.0 mm polypropylene label. Printed in black. 1.5 mm chemical indicator line, printed with EO reactive ink (Color change to green). Product code and batch number, process for intended use and bacterial strain.
On product's box: product code, batch number, bacterial load and manufacture and expiration date.

Possible target markets
Healthcare and Industries.

Precautions
The positive biological indicator can be autoclaved at 121 ºC for at least 20 minutes, at 132 ºC for at least 15 minutes in gravity displacement steam sterilization, or at 134 ºC for at least 10 minutes in vacuum steam sterilizer.

Do not store the product near sterilizing agents.
Do not expose this product to Steam, Dry Heat, Radiation or any sterilization process other than EO.

-

Manufacturer: BF MEDİKAL SANAYİ İTHALAT İHRACAT TİCARET LTD.ŞTİ.
Feridun Çelik Mah. 1743. Sok. No:6/B
Altındağ Ankara/TURKEY 06360
export@sterivision.com.tr

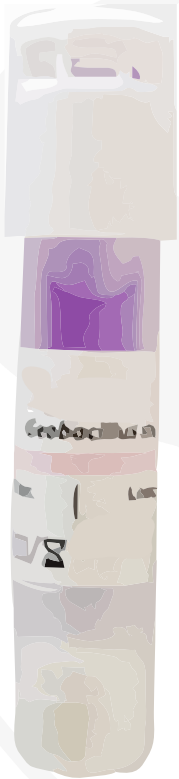
SteriVision
STERILIZATION PRODUCTS

Data Sheet

Biological Indicators

SVPLBI20M

For Plasma Sterilization



Biological Indicators
For Plasma Sterilization

SVPLBI20M

Product Description

SVPLBI20M biological indicator is specifically designed for the monitoring of Hydrogen Peroxide sterilization processes. If the sterilization process was not successful, the indicator media will change from purple to yellow after incubation at 60±2°C, thus indicating the presence of live *Geobacillus stearothermophilus* spores.

Recommended use

Sterilization process indicator, to indicate attainment of conditions for sterilization.

Specifications

If sterilization process was not successful, the purple culture media will change to a greenish gray and then to yellow, after incubation at 60±2°C, thus showing the presence of live *Geobacillus stearothermophilus* ATTC 7953 spores. If the sterilization process is successful, the culture medium will remain purple after incubation process. The final negative result is obtained after 20 minute of incubation.

Applicable standards

ISO 13485
ISO 9001
ISO 11138-1 Sterilization of health care products – Biological indicators – Part 1: General requirements
ISO 11138-3 Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes

Important

You should use SVPLBI20M Steam biological indicators for only monitoring plasma sterilization.

Storage

Store it in a dark place and temperatures between
-15-30ºC,
-35-60 % relative humidity.
Do not freeze.
Do not store these biological indicator near sterilizing agents or other chemical products.

Shelf Life

24 month. Available on box.

Important

A color change to yellow of the growth indicator media means a sterilization process failure has occurred. If within 20 minutes there is no color change in the processed indicators, a final negative result is made (the sterilization process was acceptable).

Disposal

Discard biological indicators after use according to your country's healthcare and safety regulations. The positive biological indicator can be autoclaved at 121ºC for at least 20 minutes, or at 132ºC for 15 minutes in a gravity displacement steam sterilizer, or at 134ºC for 10 minutes in a vacuum assisted steam sterilizer.

Manufacturer: BF MEDİKAL SANAYİ İTHALAT İHRACAT TİCARET LTD.ŞTİ.
Feridun Çelik Mah. 1743. Sok. No:6/B
Altındağ Ankara/TURKEY 06360
export@sterivision.com.tr

SteriVision
STERILIZATION PRODUCTS

SVPLBI1H

Self-Contained Biological Indicator.
Rapid Readout Fluorescence System.

Usage
Monitoring plasma or vaporized Hydrogen Peroxide sterilization processes (H2O2).

Applicable Regulation
ISO 11138-1:2006 and IRAM 37102-1:1999.

Classification
Class 1, according to risk.

Authorization
Designed under Quality Management System standards ISO 13485:2003/NS-EN ISO 13485:2012. ANMAT (Argentinean National Administration of Drugs, Food and Medical Technology) PM 1614-1.

Measurement System
Fluorescent Glow, 1 Hour

Characteristics
Polypropylene random copolymer tube: 50.0 mm high x 8.5 mm external diameter. Wall thickness: 0.5 mm
Polypropylene cap: 10.5 mm external diameter, 16.5 mm high. Wall thickness: 1.0 mm
Glass ampoule: 35.0 – 38.0 mm high. mm. External diameter: 6.5 mm. Wall thickness: 0.2 – 0.3 mm.
Culture medium 0.5 – 0.7 ml, purple color.
Cap filter: polyethylene fibers, 160 g/m2 , 16.0 mm diamet .
Polyethylene fibers: 5.0 x 20.0 mm, 160 g/m2
.≥ 10^6 Geobacillus stearothermophilus ATCC 7953 spores per vial.
Final fluorescence reading is performed after 2-hour incubation at 60 ºC (sensitivity: 97 %).
An optional visual pH color change confirmation could be performed after 48 hours of incubation. If sterilization process has not been successful, culture medium will change to a greenish color first, and then to yellow during incubation at 60 ºC, thus showing the presence of living spores. If sterilization process is successful culture medium will remain purple after the incubation process.
7-day readout is optional and not intended to be routinely performed; it is an initial validation of the 2-hour reading. Fluorescence results may be compared to the 7-day visual reading.
NOTE: If 7-day readout is performed, a humidified environment will be required to prevent medium from drying out.
D-Value: 2 mg/l H2O2, 50 ºC.

Environmental conditions during manufacture
Room temperature 15-30 ºC, RH 30-80 %. Sterility conditions are necessary only during the inoculation process performed in laminar flo .

Storage conditions
Under next condition: T = 10-30 ºC, RH = 30-80 %, In the original box to best stored.

Transportation conditions
Storage conditions should be strictly followed.
Products should be transported in closed and reinforced boxes in order to avoid damages. Product transportation does not represent any risk for human health.

Labelling
On product: 17.0 mm x 33.0 mm polypropylene label. Printed in black. 1.5 mm chemical indicator line, printed with Hydrogen Peroxide reactive ink (Color change to green). Product code and batch number, process for intended use and bacterial strain.
On product's box: product code, batch number, bacterial load, manufacture and expiration date.

Packing
50 units per box.
Packing information: product code and description, process for intended use, presentation, classification according to regulation, manufacturer information and data on box´s label. Note: manufacture date is calculated by subtracting 24 months to the expiration date.

Possible target markets
Healthcare and Industries.

Precautions
The product should not be stored near sterilizing agents.
This product must not be exposed to EO, dry heat, radiation or any sterilization process other than hydrogen peroxide.

Positive biological indicator can be sterilized at 121°C for at least 20 minutes, at 132°C for at least 15 minutes in gravity
Displacement steam sterilization, or at 134°C for at least 10 minutes in vacuum steam sterilizer.

-

Manufacturer: BF MEDİKAL SANAYİ İTHALAT İHRACAT TİCARET LTD.ŞTİ.
Feridun Çelik Mah. 1743. Sok. No:6/B
Altındağ Ankara/TURKEY 06360
export@sterivision.com.tr

SteriVision
STERILIZATION PRODUCTS

Data Sheet

Biological Indicators

SVPLBI24H

For Plasma Sterilization

Biological Indicators
For Plasma Sterilization

SVPLBI24H

Product Description

SVPLBI24H biological indicator is specifically designed for the monitoring of Hydrogen Peroxide sterilization processes. If the sterilization process was not successful, the indicator media will change from purple to yellow after incubation at 60±2°C, thus indicating the presence of live *Geobacillus stearothermophilus* spores.

Recommended use

Sterilization process indicator, to indicate attainment of conditions for sterilization.

Specifications

If sterilization process was not successful, the purple culture media will change to a greenish gray and then to yellow, after incubation at 60±2°C, thus showing the presence of live *Geobacillus stearothermophilus* ATTC 7953 spores. If the sterilization process is successful, the culture medium will remain purple after incubation process. The final negative result is obtained after 24 hours of incubation.

Applicable standards

ISO 13485
ISO 9001
ISO 11138-1 Sterilization of health care products – Biological indicators – Part 1: General requirements
ISO 11138-3 Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes

Important

You should use SVPLBI24H Steam biological indicators for only monitoring plasma sterilization.

Storage

Store it in a dark place and temperatures between
-15-30ºC,
-35-60 % relative humidity.
Do not freeze.
Do not store these biological indicator near sterilizing agents or other chemical products.

Shelf Life

24 month. Available on box.

Important

A color change to yellow of the growth indicator media means a sterilization process failure has occurred. If within 24 hours there is no color change in the processed indicators, a final negative result is made (the sterilization process was acceptable).

Disposal

Discard biological indicators after use according to your country's healthcare and safety regulations. The positive biological indicator can be autoclaved at 121ºC for at least 20 minutes, or at 132ºC for 15 minutes in a gravity displacement steam sterilizer, or at 134ºC for 10 minutes in a vacuum assisted steam sterilizer.

Manufacturer: BF MEDİKAL SANAYİ İTHALAT İHRACAT TİCARET LTD.ŞTİ.
Feridun Çelik Mah. 1743. Sok. No:6/B
Altındağ Ankara/TURKEY 06360
export@sterivision.com.tr

SteriVision
STERILIZATION PRODUCTS