| TECHNICAL DATA SHEET<br>BIO-CHECK 98.B2 / BIO-CHECK 98.B4 | Mod. ST73 EN |
|---|---|
| | Rev. 8 |
| | August 2021 |
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The international standards require a systematic control mechanism of sterilization equipment through the use of biological indicators.
BIO-CHECK biological indicators are designed to verify the reliability of the equipment used for STEAM and ETHYLENE OXIDE (EO) sterilization quickly and safely.

Biological indicators contain bacterial spores on paper support, inserted into a small tube of thermoplastic material containing colture liquid. This tube includes a small glass vial filled with a special extract with a color indicator which turns to yellow when spores grow.

## TEST PROCEDURE

After having filled the label by writing the sterilizer number (in case of having more than one), load number and processing date, pack the BIO-CHECK along with materials to be sterilized in an appropriate package according to recommended sterilization practices.
Place the package in those areas which are considered most inaccessible for the sterilizing agent (e.g., the center of the load and areas near the door).
Sterilize as usual.
After the sterilization process has finished, open the sterilizer door, wait five minutes and remove the BI from the package. Let the BI cool down until it reaches room temperature.
Check the Process Indicator on BI label.
A color change to brown (BIO-CHECK 98.B4) indicates that the BI has been exposed to Steam.
A color change to green (BIO-CHECK 98.B2) indicates that the BI has been exposed to Ethylene Oxide.
IMPORTANT: This color change does not evidence the process effectiveness to achieve sterility. If the Process Indicator color has not changed, check the sterilization process.
Press the lid to seal the tube. Crush the ampoule contained in the BI with an individual ampoule crusher or with the ampoule crusher placed within the incubator´s incubation area. Then shake the tube down vigorously, with movements similar to those performed to lower the temperature in a mercury thermometer, until the medium reaches the base of the tube and soaks the spore carrier entirely.
Finally, place the BI in the incubator. IMPORTANT: Use a non-sterilized BI as a positive control at least once per day, when a sterilization cycle is run. The positive control ensures that correct incubation conditions were met; capability of medium to promote rapid growth; viability of spores has not been altered due to improper storage temperature, humidity or proximity to chemicals and proper functioning of ECS Caronte Auto-Reader Incubators.

Both, the positive control indicator and the processed indicator, should belong to the same batch.
Incubate the processed indicator and the positive control indicator in the appropriate ECS Caronte Auto-Reader Incubators for a maximum of 24 hours at 60±2 °C (STEAM biological indicators) and a maximum of 48 hours at 37±2 °C (EO biological indicators) for super rapid readout.
NOTE: Holding time between sterilization and incubation should not exceed a 7-day period.

## INTERPRETATION OF THE COLOR CHANGE

Examine the indicator at regular intervals to test each color change. The color change: from purple to yellow (STEAM biological indicators) or from blue to yellow (EO biological indicators) indicates bacterial growth.
No color change indicates a correct sterilization.

## ADVANTAGES

- BIO-CHECK biological indicators are easy to use and give visible results within 24/48 hours (see below table) without any transfer to the lab.
- BIO-CHECK biological indicators allow economic saving.
- BIO-CHECK biological indicators are hermetically sealed in order to prevent any risk of contamination.
- BIO-CHECK biological indicators' labels report a color change indicator that changes color if the vial has been put through process.
- BIO-CHECK biological indicators' labels report lot number and vial deadline.

## PACKAGING

Primary packaging: 100 units per box
ON DEMAND : 10 or 20 units in a plastic bag

## STORAGE CONDITIONS

Store BIO-CHECK biological indicators away from direct sunlight in a controlled temperature environment (10 °C to 30 °C) and humidity between 30% and 80%. Do not freeze. Do not store the biological indicators next to sterilizing agents or other chemical products.

## PRODUCT SHELF-LIFE

BIO-CHECK 98.B2 and BIO-CHECK 98.B4 can be used for a period of 24 months from production date. Packaging characteristics remain unaltered if good conservation, use and storage instructions are respected.

| Code | Sterilization | Type of spores | Incubation temperature | Incubation time |
|---|---|---|---|---|
| BIO-CHECK 98.B4 | STEAM | Geobacillus Stearothermophilus $10^6$ ATCC 7953 | 60±2 °C | 24 hours |
| BIO-CHECK 98.B2 | EO | Bacillus Atrophaeus $10^6$ ATCC 9372 | 37±2 °C | 48 hours |

TO WHOM IT MAY CONCERN

**CONFORMITY DECLARATION**

The undersigned E.C.S. S.r.l. having its legal premises in Via Como, 71 – 23883 Brivio (LC), in the name of Mr. IVANO REDAELLI, as General Manager

**DECLARES**

that biological indicators BIO-CHECK 98.B2 and BIO-CHECK 98.B4 are manufactured in compliance with the following directives:

- UNI EN ISO 11138 (current edition) "Sterilization of health care products - Biological Indicators - Part 1: General requirements";
- UNI EN ISO 11138 (current edition) "Sterilization of health care products - Biological Indicators - Part 2: Biological indicators for ethylene oxide sterilization processes";
- UNI EN ISO 11138 (current edition) "Sterilization of health care products - Biological Indicators - Part 3: Biological indicators for moist heat sterilization processes";
- European pharmacopoeia (current edition), Official pharmacopoeia of the Italian Republic (current edition);
- EN ISO 11140 (current edition) "Sterilization of health care products - Chemical Indicators – Part 1: General requirements" for the parts applicable to process indicators Class 1.

We also declare that BIO-CHECK 98.B2 and 98.B4 are not medical devices and therefore they do not fall under the requirements of the European Directive 93/42/ECC and further modifications.

Brivio, August 2021

E.C.S. S.r.l.