Biological indicator EN for the reprocessing of endoscopes (load carrier)

Product information

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Field of application: EN is a biological indicator, designed for the validation and routine monitoring of cleaning and disinfection processes of endoscope washer disinfectors (WD).

Features: EN indicators contain populations of Enterococcus faecium and are contaminated with test soil according to ISO 15883-5.

Conformity: Biological indicator EN in compliance with the requirements of ISO 15883-5

Specifications:

Organism: ***Enterococcus faecium***
Mean population (cfu): ≥ ***1,0 x 10^9***
Protein content: ***> 5.000 µg / carrier***
Carrier material: ***stainless steel (appr. 70 x 9 x 1 mm)***
Primary packaging: ***paper / foil***
Organic burden: ***defibr. sheep blood + additives***
Shelf life: ***3 months from the date of manufacturing***

Storage: + 4 °C to + 8 °C

Disposal: After the disinfection process, dispose of with domestic waste.

Minimum order quantity: 5 pcs

Order No: BI-EN-14001

Example of use:

1. For the performance assessment of endoscope WD processes, take the biological indicators out of their pouches and attach them firmly to representative spots on the charging trolley.
   It is recommended to place 2 indicators in the upper part of the usable space, 2 indicators in the lower part and 1 in the small parts basket.
   Use one indicator for verifying the growth performance after transport and shipping. Do not process this control indicator!
2. Once the indicators have been fastened, sanitize your hands.
3. Select the disinfection program. Start the program.
4. When the disinfection process is finished, aseptically remove the indicators from the WD. In case there are no sterile tweezers available, use sterile one-way gloves.
   Cut the cable ties. Make sure to touch the indicators merely on the outer edge close to the drill hole.
5. Place each indicator in a separate plastic tube and cap the tube.
   Make sure the drill hole is pointing upwards.
   Sanitize your hands before transferring the next indicator.
6. Incubation: 4 days at 35 °C ± 2 °C.
   (e.g. incubate with an Enterococcus selective nutrient media)
7. Daily check all tubes for growth of the test organism.
8. Note down the results. The results are only valid if the growth control shows typical growth.

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