

Biological indicator SIMICON DH/HL for dry heat sterilization

Product information

Field of application:	SIMICON DH/HL is a biological indicator, which is designed for the validation and the routine monitoring of dry heat sterilization processes.
Features:	SIMICON DH/HL indicators contain populations of <i>Bacillus subtilis</i> .
Conformity:	Biological indicator SIMICON DH/HL in compliance with the requirements of ISO 11138-4.
Specifications:	<i>Organism: Bacillus subtilis</i> <i>Mean population: $\geq 10^6$ cfu</i> <i>Carrier material: filter paper</i> <i>Primary packaging: medical paper</i> <i>Shelf life: 24 months from the date of manufacturing</i> <i>Resistance characteristics - dry heat 160 °C:</i> <i>$D_{160\text{ °C}}$-value: $\geq 2,0$ min</i> <i>z-value: ≥ 20 °C</i>
Storage:	Store at a temperature between + 18 °C and + 25 °C and a relative humidity between 35 % and 70 %. Protect from solar radiation and direct contact with any sterilant.
Disposal:	After use, dispose with domestic waste.
Packing unit:	50, 100, 250 pcs.
Order No:	BI-HL-2001-E

Example of use:

1. For the monitoring of the performance of dry heat sterilization processes place the biological indicator into a most difficult to sterilize medical device (e.g. instruments box, glass cylinder, porcelain vessel).
2. Each sterilization program must be tested and assessed separately.
3. Place the indicators at representative spots of a typical load. E.g.
 - box with indicator no. 2 at the left front corner
 - box with indicator no. 3 at the upper left corner in the rear
 - glass cylinder with indicator no. 4 at the upper right corner in the rear
 - porcelain vessel with indicator no. 5 and 6 at the left front cornerOne indicator is meant to be a growth and transport control. Do not sterilize the growth control indicator.
4. Check temperature and preset running time.
WHO-recommendation for dry heat sterilization:
180 °C - 30 min
5. Start the sterilization
6. When the program is finished transfer the sterilized indicator strips and the growth control indicator into tubes with 7-10 ml TSB-broth. It is important to work aseptically when transferring the indicator strips.
7. Incubate the spore strips for 7 days at a temperature of 33 °C \pm 3 K.
8. Daily check all tubes for growth and especially check for specific growth of the test organism.
9. Note down the results. The results are only valid if the growth control indicator shows typical growth.