

Biological indicator

Technical data sheet

1. Administrative information about the company		Date of issue : 06/06/2016
1.1	Name : Hygitech SAS	
1.2	Complete address : 25 rue Bleue 75009 PARIS – FRANCE	Phone: +33 1 48 01 32 89 Fax : +33 1 48 01 32 80 e-mail : info@hygitech.fr Web site : www.hygitech.fr
1.3	Contact information Materiovigilance : Claudia Régnier	Phone : +33 1 45 91 31 82 Fax : +33 1 48 65 67 23 e-mail : qualite@hygitech.fr
2. Information about the equipment		
2.1	Trade name: Biological indicator	
2.2	Class of MD : N/A European Directive: N/A According Annex n° N/A Notified body: N/A Date of first launch on the UE market: 2016-05 Manufacturer : HYGITECH	
2.3	Product description : <p>The HYGITECH biological indicators are designed to control the efficiency of various processes of sterilisation by saturated vapour between 121 and 135°C. They are inoculated with viable bacterial spores of <i>GeoBacillus Stearothermophilus</i> and respond to performance specifications and quality indicated in ISO 11138. The biological indicators are compatible with the HYGITECH Dry Block Incubator, used to incubate the indicator vials between 55 and 60°C to determine the effectiveness of sterilisation.</p> <p>Color Change: violet to</p> <p>Operation Condition: 55°C-60°C – 24 hours</p> <div style="text-align: center;">  </div>	

2.4	Packaging : <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <thead> <tr style="background-color: #f4a460;"> <th style="width: 25%;">Reference</th> <th style="width: 25%;">OU Order unit</th> <th style="width: 25%;">CARTON</th> <th style="width: 25%;">MOQ Minimum order quantity</th> </tr> </thead> <tbody> <tr> <td>HY-80037</td> <td>Box of 10 units</td> <td>20 boxes per carton</td> <td>1 box of 10 units</td> </tr> </tbody> </table> Labelling : Unknown	Reference	OU Order unit	CARTON	MOQ Minimum order quantity	HY-80037	Box of 10 units	20 boxes per carton	1 box of 10 units										
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2.9	Field - Indications: Unknown																		
3. Method of sterilizing																			
	Sterile : NO Sterilization method: N/A																		
4. Storage conditions																			
	Normal conditions of storage: Store in a dry environment and at room temperature. Special precautions: Keep this product away from direct sunlight. Shelf life: 3 years Presence of temperature indicators: NO																		
5. Safety in use																			
5.1	Technical security: N/A																		
5.2	Biosecurity: N/A																		
6. Advices of use																			
	Refer to the manual for more information on the instructions for use, indications, precautions and contra-indications																		
7. Additional product information																			
	Single use: yes																		
8. Related documents																			
	Unknown																		