


Bowie Dick sterilisation test

Technical data sheet - Medical Device

1. Administrative information about the company		Date of issue: 27/10/2021
1.1	Name : Hygitech SAS	
1.2	Complete address : 109B Avenue Charles de gaulle 92200 Neuilly sur seine 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: Bowie Dick sterilisation test	
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: 2012_03 Manufacturer : HYGITECH	
2.3	<p>Product description :</p> <p>The Bowie Dick pack controls the proper functioning of the autoclave and verifies possible defects during Bowie Dick's cycle. The Bowie&Dick tests the autoclave's capacity to sterilize porous or packaged items (type B items).</p> <p>Bowie-Dick test packs should be used daily, on a specific cycle (in an empty autoclave), especially after a sterilizer is installed, relocated, after sterilizer malfunction, after sterilization process failures, and after any major repairs of the sterilizer.</p> <p>Especially, single use Bowie Dick pack points out the presence of air leaks in the autoclave immediately and accurately.</p> <p>Aim of the test: Steam is forced to penetrate successive layers of card and cause a reaction on a piece of paper printed with indicator ink. Presentation: The ready-to-use package contains multiple layers of card, in the centre of which is a chemical indicator sheet with thermochromatic ink.</p> <p>Color Change: Yellow to Black</p> <p>Operation Condition: 134°C, 3.5 minutes</p>	
		

2.4	Packaging : <table border="1" data-bbox="406 302 1380 414"> <thead> <tr> <th data-bbox="406 302 555 376">Reference</th> <th data-bbox="555 302 778 376">OU Order unit</th> <th data-bbox="778 302 1149 376">CARTON</th> <th data-bbox="1149 302 1380 376">MOQ Minimum order quantity</th> </tr> </thead> <tbody> <tr> <td data-bbox="406 376 555 414">HY-80009</td> <td data-bbox="555 376 778 414">Box of 20 units</td> <td data-bbox="778 376 1149 414">Carton of 9 boxes of 20 units</td> <td data-bbox="1149 376 1380 414">1 box of 20 units</td> </tr> </tbody> </table> Labelling : Unknown	Reference	OU Order unit	CARTON	MOQ Minimum order quantity	HY-80009	Box of 20 units	Carton of 9 boxes of 20 units	1 box of 20 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: 5 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																		