

Mini Bowie & Dick Sterilization Test

Technical Datasheet – Medical Device

1. Administrative information about the company Date of issue : 11/09/2023

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2. Information about the equipment

2.1	Name : Mini Bowie & Dick Sterilisation test	
2.2	Trade name: Mini Bowie Dick Test	
2.3	CLADIMED Nomenclature Code : E52IB03	
2.4	LPPR* Code (ex TIPS if applicable) : N/A	
2.5	Class of MD : N/A Notified body: N/A ISO Standard : 11140 - 4 : 2014 - Type 2 Date of first launch on the UE market: September 2023 Manufacturer : HYGITECH	

Device Description :

The mini Bowie & Dick test checks that the autoclave is operating correctly and checks for possible faults during the Bowie & Dick cycle. Bowie & Dick tests the autoclave's ability to sterilize porous or packaged items (type B items). The Bowie & Dick test should be used daily, and more specifically after installation, relocation or the occurrence of a technical problem on the autoclave. The single-use Bowie & Dick indicates the presence of air leaks in the autoclave immediately and reliably.

- Principle : The steam penetrates several layers of cardboard and causes a reaction on a sheet of paper printed with thermochromatic ink.
- Presentation : The ready-to-use package contains several layers of cardboard, in the center of which is a card printed with heat-sensitive ink.
- Color change : Blue to Pink
- Operating conditions : 134°C, 3.5 minutes

Thanks to a reduced size - 10.5 x 6.5 x 0.5 cm – the Mini Bowie Dick guarantees space saving within the autoclave.

2.7	<p>Packaging</p> <p>Product Code : HY-800091 Order Unit : 50 units box Labelling :</p>
2.8	<p>Device composition, dimensions and accessories :</p> <p>Eléments : mini Bowie & Dick sterilization test Materials : Paperboard, indicator ink, Bowie & Dick sheet Dimensions : 10.5 x 6.5 x 0.5 cm</p> <p>Presence of :</p> <p>Latex : NO Phtalates (DEHP) : NO Products of animal or organic origin : NO</p>
2.9	<p>Field - Indications: Not specified</p>
<p>3. Sterilization process</p> <p>Sterile: NO Device sterilization method: N/A</p>	
<p>4. Storage and keeping conditions</p> <p>Normal storage and keeping conditions: Store in a dry environment at room temperature (between 10 and 40°C). Special precautions: Do not expose to direct sunlight.</p>	

Shelf life : 5 years Presence of temperature indicators: NO	
5. Safety in use	
5.1	Technical safety: N/A
5.2	Biological safety: N/A
6. Directions for use	
Please refer to the package insert for further information on directions for use, indications, precautions and contraindications.	
7. Additional product information	
Single use: YES	
8. Additional documents	
No information	