


## Helix sterilisation test

### Technical data sheet

<b>1. Administrative information about the company</b>		<b>Date of issue : 29/06/2021</b>
<b>1.1</b>	<b>Name :</b> HYGITECH SAS	
<b>1.2</b>	<b>Complete address :</b> 109 bis avenue Charles de Gaulle, 92200 Neuilly-sur-Seine FRANCE	<b>Phone:</b> +33 1 48 01 32 89 <b>Fax :</b> +33 1 48 01 32 80 <b>e-mail :</b> info@hygitech.fr <b>Web site :</b> www.hygitech.fr
<b>1.3</b>	<b>Contact information</b> <b>Materiovigilance :</b> Claudia Régnier	<b>Phone :</b> +33 1 45 91 31 82 <b>Fax :</b> +33 1 48 65 67 23 <b>e-mail :</b> qualite@hygitech.fr
<b>2. Information about the equipment</b>		
<b>2.1</b>	<b>Trade name:</b> Helix sterilisation test	
<b>2.2</b>	<b>Class of MD :</b> N/A <b>European Directive:</b> N/A <b>According Annex n°</b> N/A <b>Notified body:</b> N/A <b>Date of first launch on the UE market:</b> 2012_05 <b>Manufacturer :</b> HYGITECH	
<b>2.3</b>	<b>Product description :</b>  The Helix test checks the ability of the autoclave to sterilise hollow objects such as suction or irrigation tubes. The tests should be carried out daily on a specific cycle, vacuum autoclave, so that the different sterilisation cycles of the day can then be carried out.  <b>Features :</b> <u>Presentation:</u> The test consists of a 1.5 metre long tube open at one end. The other end is closed by a hermetically sealed capsule which contains a strip printed with an indicator ink. <u>Procedure:</u> Subject this test to a sterilisation cycle of 134°C for 3 to 5 minutes to simulate the sterilisation performance of an autoclave for a "complex" medical device <u>Principle:</u> The steam should penetrate the inside of the coiled tube, which is deliberately narrow, and cause a reaction on the strip printed with the indicator ink. If the ink on the strip turns completely black then the sterilisation is successful. However, if the ink is still yellow or partially yellow then the test is considered negative (this means that the vapour has not penetrated properly to the indicator). It is then advisable to call in a professional repairer who will be able to validate the origin of the anomaly (incorrect calibration, contact time too low, etc.). <u>Traceability:</u> To ensure traceability, it is important to keep each test result in a register. The objective being to always prove the good functioning of the equipment in case of infection of a patient. <u>Packaging:</u> Box of 100 strips + 1 tube or 250 strips + 1 tube.  <b>Benefits :</b> <ul style="list-style-type: none"> <li>• Reliable : Helix tests guarantee good sterilisation and proper functioning of the autoclave, even for complex (hollow) products</li> <li>• Easy to read : Colour-coded for clear reading, legible and easy-to-interpret result</li> <li>• Tracking : HYGITECH strips are composed of an adhesive part for easy storage in the register</li> </ul>	

																									
<b>2.4</b>	<p><b>Packaging :</b></p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr style="background-color: #f4a460;"> <th style="padding: 5px;">Reference</th> <th style="padding: 5px;">OU Order unit</th> <th style="padding: 5px;">CARTON</th> <th style="padding: 5px;">MOQ Minimum order quantity</th> </tr> </thead> <tbody> <tr> <td style="padding: 5px;">HY-80036</td> <td style="padding: 5px;">Box of 100 tests</td> <td style="padding: 5px;">180 Boxes of 100 tests</td> <td style="padding: 5px;">1 box of 100 tests</td> </tr> <tr> <td style="padding: 5px;">HY-800361</td> <td style="padding: 5px;">Box of 250 tests</td> <td style="padding: 5px;">180 Boxes of 250 tests</td> <td style="padding: 5px;">1 box of 250 tests</td> </tr> </tbody> </table> <p><b>Labelling :</b> Unknown</p>	Reference	OU Order unit	CARTON	MOQ Minimum order quantity	HY-80036	Box of 100 tests	180 Boxes of 100 tests	1 box of 100 tests	HY-800361	Box of 250 tests	180 Boxes of 250 tests	1 box of 250 tests												
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<b>2.9</b>	<b>Field - Indications:</b> Unknown																								
<b>3. Method of sterilizing</b>																									
	<p><b>Sterile :</b> NO  <b>Sterilization method:</b> N/A</p>																								
<b>4. Storage conditions</b>																									
	<p><b>Normal conditions of storage:</b> Store in a dry environment and at room temperature.  <b>Special precautions:</b> Keep this product away from direct sunlight  <b>Shelf life:</b> 5 years  <b>Presence of temperature indicators:</b> NO</p>																								
<b>5. Safety in use</b>																									
<b>5.1</b>	<b>Technical security:</b> N/A																								
<b>5.2</b>	<b>Biosecurity:</b> N/A																								
<b>6. Advices of use</b>																									

	Refer to the manual for more information on the instructions for use, indications, precautions and contra-indications
<b>7. Additional product information</b>	
	<b>Single use:</b> YES
<b>8. Related documents</b>	
	Unknown