

Sterile protection sleeve


Technical data sheet

1. Administrative information about the company

Date of issue : 14/02/24

1.1	Name : HYGITECH SAS	
1.2	Complete address : 55 avenue Foch 75116 PARIS – FRANCE	Phone: +33 1 48 01 32 89 e-mail : info@hygitech.fr Web site : www.hygitech.fr
1.3	Contact information Materiovigilance : Said BOUTOUGHMAS	Phone : +33 1 45 91 31 82 e-mail : qualite@hygitech.fr

2. Information about the equipment

2.1	Trade name: Sterile protection sleeve	
2.2	Class of MD : Class ISTERILE European Directive: MDR 2017/745 According Annex n° XI Part A Notified body: 1639 SGS BELGIUM Date of first launch on the UE market: 2010_05 Manufacturer : Hygitech	
2.3	Product description : The protection sleeve provides excellent protection for tubing while guaranteeing the best sanitary conditions. This disposable PVC sheath, specifically designed for implantologists, is both: <ul style="list-style-type: none"> • easy to put on: on account of its user-friendly packaging : An inner card enables the operator to extend the sleeve without having to touch the tube • easy to fix using the latex-free elastic bands supplied 	
		

2.4	Packaging : <table border="1" data-bbox="344 315 1484 409"> <thead> <tr> <th>Reference</th><th>OU Order unit</th><th>CARTON</th><th>MOQ Minimum order quantity</th></tr> </thead> <tbody> <tr> <td>HY-138</td><td>Box of 10 units</td><td>Carton of 8 boxes of 10 units</td><td>1 Box of 10 units</td></tr> </tbody> </table> <p>Labelling : Unknown</p>	Reference	OU Order unit	CARTON	MOQ Minimum order quantity	HY-138	Box of 10 units	Carton of 8 boxes of 10 units	1 Box of 10 units													
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2.9	Field - Indications: Unknown																					
3. Method of sterilizing																						
	Sterile : YES Sterilization method: Ethylene Oxide (EO)																					
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																						
	<ul style="list-style-type: none"> - This product is a medical device. Read the instructions on the packaging carefully before use. - This product is for single use only and must not be reused. Reuse of this product may expose the patient to an infectious risk. - Do not use the product if the packaging is damaged. - Do not resterilize this product. 																					
7. Additional product information																						
	Single use: YES																					
8. Related documents																						
	Unknown																					