

Surgical gown + 2 hand towels

Technical data sheet - Medical Device

1. Administrative information about the company

Date of issue : 14/02/2024

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: Surgical gown + 2 hand towels																																								
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: 2011_06 Manufacturer : Hygitech																																								
2.3	Product description : Superior surgical gown, • Surgically folded long internal and external side waist (4 ties total) towels provided strap fit, hypoallergenic cuffs crepe paper	 	sterile • 125 cm • Double ties on the • 2 hand • Velcro cotton • 45g																																						
2.4	Packaging : <table border="1"> <thead> <tr> <th rowspan="2">Reference</th><th>OU</th><th rowspan="2">CARTON</th><th>MOQ</th></tr> <tr> <th>Order unit</th><th>Minimum order quantity</th></tr> </thead> <tbody> <tr> <td>HY-503 - S</td><td>Box of 20 units</td><td>Carton of 2 boxes of 20 units</td><td>1 box of 20 units</td></tr> <tr> <td>HY-511- M</td><td>Box of 20 units</td><td>Carton of 2 boxes of 20 units</td><td>1 box of 20 units</td></tr> <tr> <td>HY-512 - L</td><td>Box of 20 units</td><td>Carton of 2 boxes of 20 units</td><td>1 box of 20 units</td></tr> <tr> <td>HY-513- XL</td><td>Box of 20 units</td><td>Carton of 2 boxes of 20 units</td><td>1 box of 20 units</td></tr> <tr> <td>HY-50041</td><td>Box of 50 units</td><td>Carton of 50 units</td><td>Cartons of 50 units</td></tr> <tr> <td>HY-50042</td><td>Box of 50 units</td><td>Carton of 50 units</td><td>Carton of 50 units</td></tr> <tr> <td>HY-50043</td><td>Box of 50 units</td><td>Carton of 50 units</td><td>Carton of 50 units</td></tr> <tr> <td>HY-50043</td><td>Box of 50 units</td><td>Carton of 50 units</td><td>Carton of 50 units</td></tr> </tbody> </table> Labelling : Unknown			Reference	OU	CARTON	MOQ	Order unit	Minimum order quantity	HY-503 - S	Box of 20 units	Carton of 2 boxes of 20 units	1 box of 20 units	HY-511- M	Box of 20 units	Carton of 2 boxes of 20 units	1 box of 20 units	HY-512 - L	Box of 20 units	Carton of 2 boxes of 20 units	1 box of 20 units	HY-513- XL	Box of 20 units	Carton of 2 boxes of 20 units	1 box of 20 units	HY-50041	Box of 50 units	Carton of 50 units	Cartons of 50 units	HY-50042	Box of 50 units	Carton of 50 units	Carton of 50 units	HY-50043	Box of 50 units	Carton of 50 units	Carton of 50 units	HY-50043	Box of 50 units	Carton of 50 units	Carton of 50 units
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2.8	Composition of the product, dimensions and accessories : <table border="1" data-bbox="327 309 1484 840"> <thead> <tr> <th>Elements</th><th>Material</th><th>Dimensions</th></tr> </thead> <tbody> <tr> <td>HY-503 - S Surgical gown</td><td>SMS 45g/m²</td><td>110 x 60 cm</td></tr> <tr> <td>HY-511 - M Surgical gown</td><td>SMS 45g/m²</td><td>120 x 65 cm</td></tr> <tr> <td>HY-512 - L Surgical gown</td><td>SMS 45g/m²</td><td>115 x 110 cm</td></tr> <tr> <td>HY-513 - XL Surgical gown</td><td>SMS 45g/m²</td><td>130 x 75 cm</td></tr> <tr> <td>Hand towels</td><td>Paper 40g/m²</td><td>20 x 15 cm unfolded, 11 x 4 cm creased</td></tr> <tr> <td>HY-50041 - Sterile isolation gown S</td><td>PP 30g/m²</td><td>110 x 60 cm</td></tr> <tr> <td>HY-50042 - Sterile isolation gown M</td><td>PP 30g/m²</td><td>120 x 65 cm</td></tr> <tr> <td>HY-50043 - Sterile isolation gown L</td><td>PP 30g/m²</td><td>125 x 70 cm</td></tr> <tr> <td>HY-50044 - Sterile isolation gown XL</td><td>PP 30g/m²</td><td>130 x 75 cm</td></tr> <tr> <td>Packing</td><td>Crepe paper 30g/m²</td><td>40 x 40 cm</td></tr> </tbody> </table> <table border="1" data-bbox="327 985 1476 1164"> <thead> <tr> <th colspan="3">Presence of :</th></tr> </thead> <tbody> <tr> <td>Latex</td><td><input type="checkbox"/> YES</td><td><input checked="" type="checkbox"/> NO</td></tr> <tr> <td>Phthalates (DEHP)</td><td><input type="checkbox"/> YES</td><td><input checked="" type="checkbox"/> NO</td></tr> <tr> <td>Products of animal or biological origin</td><td><input type="checkbox"/> YES</td><td><input checked="" type="checkbox"/> NO</td></tr> </tbody> </table>	Elements	Material	Dimensions	HY-503 - S Surgical gown	SMS 45g/m ²	110 x 60 cm	HY-511 - M Surgical gown	SMS 45g/m ²	120 x 65 cm	HY-512 - L Surgical gown	SMS 45g/m ²	115 x 110 cm	HY-513 - XL Surgical gown	SMS 45g/m ²	130 x 75 cm	Hand towels	Paper 40g/m ²	20 x 15 cm unfolded, 11 x 4 cm creased	HY-50041 - Sterile isolation gown S	PP 30g/m ²	110 x 60 cm	HY-50042 - Sterile isolation gown M	PP 30g/m ²	120 x 65 cm	HY-50043 - Sterile isolation gown L	PP 30g/m ²	125 x 70 cm	HY-50044 - Sterile isolation gown XL	PP 30g/m ²	130 x 75 cm	Packing	Crepe paper 30g/m ²	40 x 40 cm	Presence of :			Latex	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO	Phthalates (DEHP)	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO	Products of animal or biological origin	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
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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: N/A 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																																													