

## Surgical gown + 2 hand towels

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 ab	oout the equipment				
2.1	<b>Trade name:</b> Surgical gown + 2 hand tower	els			

2.1 Trade name: Surgical gown + 2 hand fowels

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

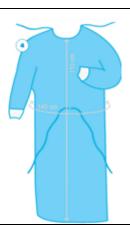
Manufacturer : Hygitech

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:

Reference	OU	CARTON	MOQ
	Order unit	CARTON	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

**Labelling:** Unknown



2.8	Composition of the product, dimensi	ions and accessorie	es:				
	Elements	Material	Dimensions				
	HY-503 - S Surgical gown	SMS 45g/m²	110 x 60 cm				
	HY-511 - M Surgical gown	SMS 45g/m²	120 x 65 cm				
	HY-512 - L Surgical gown	SMS 45g/m²	115 x 110 cm				
	HY-513 - XL Surgical gown	SMS 45g/m²	130 x 75 cm				
	Hand towels	Paper 40g/m²	20 x 15 cm unfolded, 11 x 4 cm crease				
	HY-50041 - Sterile isolation gown S	PP 30g/m²	110 x 60 cm 120 x 65 cm 125 x 70 cm 130 x 75 cm 40 x 40 cm				
	HY-50042 - Sterile isolation gown M	PP 30g/m²					
	HY-50043 - Sterile isolation gown L	PP 30g/m²					
	HY-50044 - Sterile isolation gown XL	PP 30g/m²					
	Packing	Crepe paper 30g/m²					
	Presence of :						
	Latex		☐ YES	☐ YES ☐ NO			
	Phthalates (DEHP)		☐ YES	⊠ NO			
	Products of animal or biological origin		☐ YES	⊠ NO			
			,				
2.9	Field - Indications: Unknown						
3. Method of ste	erilizing Sterile : YES						
	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						
6. Advices of us	1						
o. Advices Of US	<ul> <li>This product is a medical device. Read the instructions on the packaging carefully before use.</li> <li>This product is for single use only and must not be reused. Reuse of this product may expose the patient to an infectious risk.</li> <li>Do not use the product if the packaging is damaged.</li> <li>Do not resterilize this product.</li> </ul>						
7. Additional pro	oduct information						
	Single use: YES						
8. Related docu	l uments						
J. Kolaica acco	Unknown						