



Operating Theatre Medical™  
company limited

NL: ISOLATIEJAS - GEBREIDE MANCHET  
EN: ISOLATION GOWN - KNITTED CUFF  
FR: BLOUSE DE PROTECTION - POIGNET JERSEY  
IT: CAMICE ALTA PROTEZIONE - POLSINO IN MAGLINA  
ES: BATA AISLAMIENTO - PUÑO ALGODÓN  
DE: UNTERSUCHUNGSKITTEL - STRICKBÜNDCHEN

REF

9002378



LOT

2300374-00685



2023-09



2028-09

EC REP

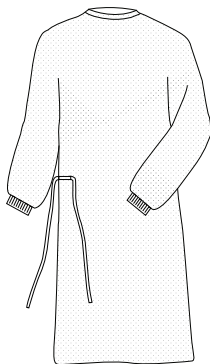
**Mono-Use NV**  
Driesstraat 30  
8790 Waregem  
Belgium



**Operating Theatre Medical**  
(Hubei) Company Limited  
Xianhong Road  
Xiantao City  
Hubei 433000  
China



**BELSCAN BV**  
Oudeheerweg 8  
9051 Gent  
Belgium  
[www.distrifund.be](http://www.distrifund.be)



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PCS

NL: GEEL  
EN: YELLOW  
FR: JAUNE  
IT: GIALLO  
ES: AMARILLO  
DE: GELB



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## EU-DECLARATION OF CONFORMITY

### in accordance with the EU Regulation 2017/745 on medical devices

We, Operating Theatre Medical (Hubei) Co. Ltd, herewith declare that the following medical device

Definition	Isolation gown is a gown worn by medical staff to minimize and protect against exposure to infective agents between medical staff and patient each other.
Description	A gown made of nonwoven fabric materials intended to be worn by healthcare providers to isolate themselves from patients. The isolation gown helps to protect the patient (e.g., burn patients) from the transfer of infectious agents carried by the healthcare provider; or it may help to protect the healthcare provider from a contagious agent which has infected the patient. This is a single-use garment.
Intended purpose	Isolation gowns are used to minimize the transmission of infective agents between medical staffs during checking and other non-invasive procedures, through prevention of dispersal of bacteria-carrying skin scales from medical staff to patient each other, and penetration of liquids to the medical staff from infective agents carried in body fluids, thereby helping to prevent infections during checking and other non-invasive procedures.
GMDN – code	35492
Classification	Class I medical device according Annex VIII, chapter III, rule 1 of the medical device Regulation (EU) 2017/745
Version	Non-sterile, single use product
Colour	White/Green/Blue /Yellow
Size	NA
Basic UDI -DI	69733012350004B
Complies with the relevant provisions of the EU Regulation 2017/745 as a class I medical device.	

Applicable Regulation Regulation 2017/745 on medical devices

Applied harmonized standards NA



The product concerned has been manufactured under a quality management system according to Annex IX Chapter I of the medical device Regulation 2017/745.

This declaration is exclusively under the responsibility of

Manufacturer - CN-MF-000001419:

**Operating Theatre Medical (Hubei) Co. Ltd**

Xianhong Road, Xiantao City

Hubei, China

Wuhan China

Place, date 2023-03-10

EC Declaration of Conformity Version: 1.2 add size item

Authorised Representative – BE-AR-000001322:  
Mono Uso N.V.

Driesstraat 30 – 8790 Waregem - Belgium

Tel +32 56 60 81 51 Fax +32 56 62 70 96

On behalf of Operating Theatre Medical (Hubei)  
Co., Ltd.

Mrs Sherry Liu  
General Manager

Legally binding signature, function



Operating Theatre Medical  
company limited

## Technical File

### Isolation Gown - Belscan Label

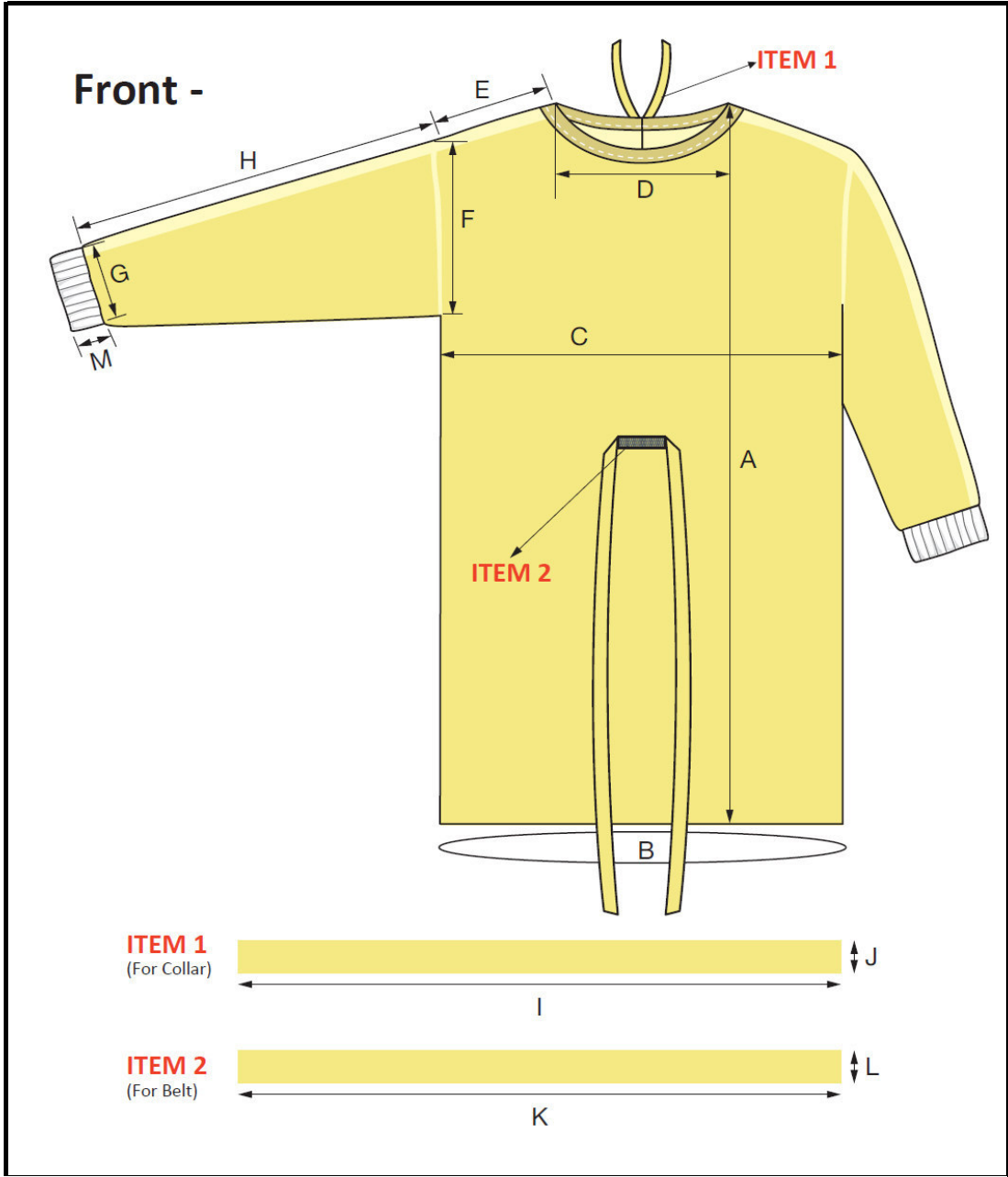
Knitted Cuff, 115x137cm, 20 gr/m2, Yellow, SMS

<b>Name of Commodity</b>		<b>Isolation Gown With Knitted Cuff / Yellow</b>					
<b>Your Art No.</b>		9002378					
<b>Classification</b>		Class I					
<b>Standard</b>		REGULATION (EU) 2017/745					
<b>Sterilization</b>		NON					
<b>Intended use</b>		Visit gown are used to minimize the transmission of infective agents between medical staffs ,visitor and patient during checking, visitation and other non-invasive procedures, through prevention of dispersal of bacteria-carrying skin scales from medical staff or visitor to patient each other, thereby helping to prevent infections during checking, visitation and other non-invasive procedures.					
<b>Character</b>							
Fixation	Stitch Way		Normal Overlock Stitch				
	Belt		- 1 Belt To Be Stitched On The Front Waist - 1 Belt To Be Stitched On Collar				
	Yarn		White				
Composition	Body	Material	SMS				
		Weight	20g/sqm (+/-2g/sqm)				
		Colour	Yellow				
	Collar <b>ITEM 1</b>	Material	SMS				
		Weight	20g/sqm (+/-2g/sqm)				
		Colour	Yellow				
	Belt <b>ITEM 2</b>	Material	SMS; Stitched				
		Weight	20g/sqm (+/-2g/sqm)				
		Colour	Yellow				
		Location	Outside Waist Belt On The Front				
	Cuff	Material	Knitted Fabric				
		Colour	White				
Size (Unit: cm)	Body		<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
		size	115 (+/-2)	137 (+/-2)	68 (+/-2)	24 (+/-2)	22 (+/-2)
	Sleeve & Cuff		<b>F</b>	<b>G</b>	<b>H</b>	<b>M</b>	
		size	26 (+/-2)	15 (+/-2)	56 (+/-2)	5(+/-1)	
	Collar <b>ITEM 1</b>		<b>I</b>	<b>J</b>			
		size	110 (+/-5)	0.8			
	Belt <b>ITEM 2</b>		<b>K</b>	<b>L</b>			
		size	180 (+10/-5)	0.8			



# Technical File

**Isolation Gown - Belscan Label**  
Knitted Cuff, 115x137cm, 20 gr/m2, Yellow, SMS





# Technical File

**Isolation Gown - Belscan Label**  
Knitted Cuff, 115x137cm, 20 gr/m2, Yellow, SMS

<b>Packing</b>			
<b>Interior</b>		10 pcs/PE Bag	
	PE Bag	<b>Material</b>	Transparent PE Bag With Normal Seal
		<b>Size</b>	25 x 29 x 6 cm ( Just For Reference )
	<b>Batch No. Label/Printing</b>	1/	Belscan Will Send The Batch NO. In An BMP-Format Together With The Purchase order
		2/	Batch No. Label Will Be Pasted/Printed At The Lower Right Corner Of PE Bag, Total One Label/PE Bag.
		3/	Black Printing
		4/	Size Of Batch No. Label: 5 x 3 cm(+/-0.5)
	<b>Inner Label</b>	1/	OTM's Artwork Will Be Pasted/Printed At The Center Of PE Bag
		2/	The Size Of Artwork Will Be 15 x 10cm (+/-1)
		3/	2 Colors Printing: Green (Pantone 2242 C) & Black

<p><b>Inner Label -</b></p> <div style="border: 1px solid black; padding: 5px;"> </div>	<p style="text-align: center;"><b>Batch No. Label/Printing(Sample) -</b></p> <div style="text-align: center;"> <p>*2300374-00685*</p> </div> <p style="text-align: center;">Location For The Inner Label/Printing &amp; Batch No. Label/Printing</p> <div style="border: 1px solid red; padding: 10px; margin-top: 20px;"> <div style="text-align: center; border-bottom: 1px dashed black; padding-bottom: 10px;"> <p style="color: red; font-weight: bold;">Inner Label/Printing</p> </div> <div style="text-align: right; padding-top: 20px;"> <p style="color: red; font-weight: bold;">Batch No. Label/Printing</p> </div> </div>
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All data mentioned-above are samples for the reference, which will be created by the information from each purchase order.



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## Technical File

### Isolation Gown - Belscan Label

Knitted Cuff, 115x137cm, 20 gr/m2, Yellow, SMS

Exterior		10 PE Bags / Carton ( Total: 100 Pcs/Carton )		
Carton	Material	5 Layer Standard Export Carton		
	Colour	Brown		
	Size	47 x 26 x 31 CM ( Just For Reference )		
	Top Lay	Material	3 Layer Corrugated Cardboard	
		Colour	Brown	
		Location	Put On The Top Of PE Bags	
	Batch No. Label/Printing	1/ Belscan Will Send The Batch NO. In An BMP-Format Together With The Purchase Order		
		2/ Batch No. Label Will Be Pasted/Printed At The Lower Right Corner Of Both Long Sides Of The Carton, Total 2 Labels/Carton.		
		3/ Black Printing		
		4/ Size Of Batch No. Label: 7 x 4 cm(+/-0.5)		
Printing	1/ OTM's Artwork Is Printed On 4 Sides Of Carton			
	2/ 2 Colors Printing: Black & Yellow (Pantone No. Yellow C)			
<b>Belscan's Artwork &amp; Batch No. Label/Printing On Carton -</b>				
<b>Suggested Storage</b>				
Temperature		Between -5°C and 40°C		
Humidity		Below 80%		
Sunlight		Keep Away From Direct Sunlight		
Edition No. --- Edit Date		Changed Description/Reason	Created/Revised By	
Edition 1.0 --- 2023.08.21		New	OTM China	