

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



Mono-Uso 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





PCS

NL: GEEL EN: YELLOW FR: JAUNE IT: GIALLO

ES: AMARILLO DE: GELB



Factory: Xianhong Road, Xiantao City, Hubei, China.

Office: Room No.1101, Licheng Commercial Centre, No. 30, Jianmei Street. Jiangan District, Wuhan 430015, China

CE

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

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

Place, date 2023-03-10

EC Declaration of Conformity Version: 1.2 add size item

工厂: 湖北省仙桃市仙洪路

公司: 武汉市江岸区健美街30号立城中心商务楼1101室 邮编430015

电话: 86 27 8575 2562 / 8557 7071 传真: 86 27 8578 0240 邮箱: sales@otmedical.com



Technical File

Isolation Gown - Belscan Label

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

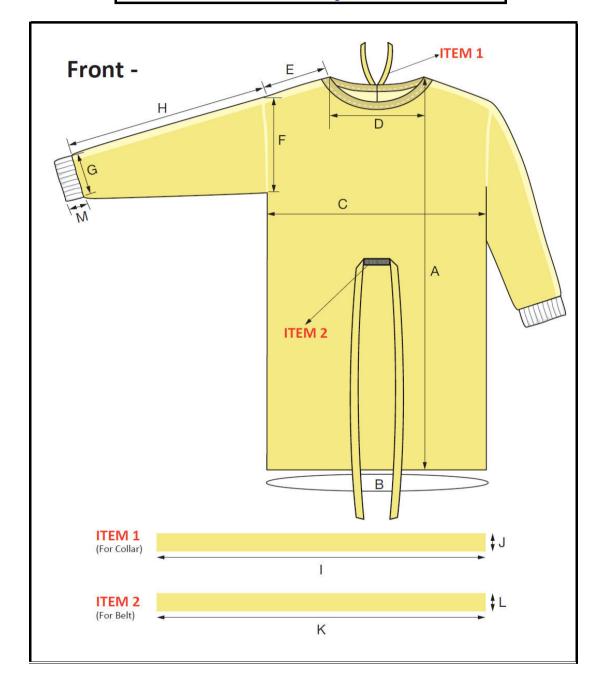
Name of Commo	odity	Isolation Gov	wn With Knit	ted Cuff / Ye	ellow			
Your Art No.		9002378						
Classification		Class I						
Standard		REGULATIO	N (EU) 2017/	745				
Sterilization		NON						
Intended use		medical staffs procedures, th medical staff	e used to mining visitor and parough prevent or visitor to pang, visitation a	atient during of ion of dispers tient each oth	checking, visit al of bacteria- ner, thereby he	tation and othe carrying skin lping to preven	er non-invasive scales from	
Character	<u> </u>		L					
Fixation	Stitch	Stitch Way		Normal Overlock Stitch				
	В	Belt		- 1 Belt To Be Stitched On The Front Waist - 1 Belt To Be Stitched On Collar				
	37			se Stitched O	n Collar			
Composition	Ya	arn Material	White					
Composition	Body	Weight	SMS					
		Colour	20g/sqm (+/-2g/sqm) Yellow					
		Material	SMS					
	Collar	Weight	20g/sqm (+/-2g/sqm)					
	ITEM 1	Colour	Yellow					
		Material	SMS; Stitched					
	Belt	Weight	20g/sqm (+/-2g/sqm)					
	ITEM 2	Colour	Yellow					
		Location	Outside Waist Belt On The Front					
	Cuff	Material	Knitted Fabri	ic				
	Cuii	Colour	White					
Size	Body		A	В	C	D	E	
(Unit: cm)	Body	size	115 (+/-2)	137 (+/-2)	68 (+/-2)	24 (+/-2)	22 (+/-2)	
	Sleeve		F	G	H	M		
	& Cuff	size	26 (+/-2)	15 (+/-2)	56 (+/-2)	5(+/-1)		
	Collar		I	J				
	ITEM 1	size	110 (+/-5)	0.8				
	Belt		K	L				
	ITEM 2	size	180 (+10/-5)	0.8				



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





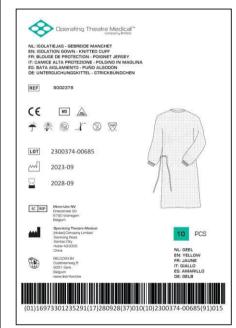
Technical File

Isolation Gown - Belscan Label

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

Packing			
Interior			10 pcs/PE Bag
		Material	Transparent PE Bag With Normal Seal
		Size	25 x 29 x 6 cm (Just For Reference)
			1/ Belscan Will Send The Batch NO. In An BMP-Format Together
			With The Purchase order
		Batch No. Label/Printin	2/ Batch No. Label Will Be Pasted/Printed At The Lower
	PE Bag	g g	Right Corner Of PE Bag, Total One Label/PE Bag.
		0	3/ Black Printing
			4/ Size Of Batch No. Label: 5 x 3 cm(+/-0.5)
			1/ OTM's Artwork Will Be Pasted/Printed At The Center Of PE Bag
		Inner Label	2/ The Size Of Artwork Will Be 15 x 10cm (+/-1)
			3/2 Colors Printing: Green (Pantone 2242 C) & Black
Townson Tools of		•	D-4-1-N- I -1-1/D-2-42(C1-)

Inner Label -



All data mentioned-above are samples for the reference, which will be created by the information from each puchase order.

Batch No. Label/Printing(Sample) -



*2300374-00685

Location For The Inner Label/Printing & Batch No. Label/Printing





Technical File

Isolation Gown - Belscan Label

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

Exterior		1	10 PE Bags / Carton (Total: 100 Pcs/Carton)		
		Material	5 Layer Standard Export Carton		
		Colour	Brown		
		Size	47 x 26 x 31 CM (Just For Reference)		
			Material 3 Layer Corrugated Cardboard		
		Top Lay	Colour Brown		
			Location Put On The Top Of PE Bags		
	Conton		1/ Belscan Will Send The Batch NO. In An BMP-Format Toget		
	Carton	Batch No. Label/Printin	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/Ca		
		g	3/ Black Printing		
			4/ Size Of Batch No. Label: 7 x 4 cm(+/-0.5)		
		D : :	1/ OTM's Artwork Is Printed On 4 Sides Of Carton		
		Printing	2/ 2 Colors Printing: Black & Yellow (Pantone No. Yellow C)		
Belscan's Artw	ork & Batch I	No. Label/Prin	nting On Carton -		
NL ISOLATIEJAS - GEBREIDE MANCHET EN ISOLATION GOWNE - KINITEO CUST FR. BLOUSE DE PROTECTION - POUNTE JERSEY IT: CAMICE ALTA PROTEZONE - POLISIED IN MAGCIL ER BATA ARIAMENTO - PUND ALCODON OL UNITERBUCHANDIKITTEL - STRICKBUNGOREN REF. BOCOZIE	INA A		THE MICHAETH COMPANY AND THE CONTROL OF THE CONTROL		
EN: EIGLATION GOWN - KNITTED CUFF FR. BLOUBE DE PROTECTION - POIGNET JERBEY IT: CAMICE ALTA PROTEZIONE - POLISINO IN MAGLIE	Batch No. Label/Printing No. Total Analysis	POS POS POS POS POS POS POS POS POS POS	THE SLOVER OF POPULATION FORWARD AND THE POPULATION OF THE POPULAT		
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