



the dtic

Department:
Trade, Industry and Competition
REPUBLIC OF SOUTH AFRICA

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Gowns

<p>Gown: Isolation gown? Non-sterile</p>	<p>Protective 3- layers of spunbond meltblown spunbound fabric(Top layer of spunbound polypropylene, a middle layer of meltdown polypropylene and a bottom layer of meltdown polypropylene for light fluid contact and contact Isolation, elastic cuff, Tape-tab neck closure, Tie waist, Dimensions: Extra Large (XL) Length: (from shoulder to hem) 127cm Sleeve length: (from shoulder to wrist) 62cm Belt length: 172cm Belt Width: 5cm Belt place: (neck to top of belt) 38 - 39cm WHO: Single use, fluid resistant, disposable, length mid-calf to cover the top of the boots, light colors preferable to better detect possible contamination, thumb/finger loops or elastic cuff to anchor sleeves in place. Option 1: fluid penetration resistant: EN 13795 high performance, or AAMI PB70 level 3 performance or above, or equivalent Option 2: blood borne pathogens penetration resistant: AAMI PB70 level 4 performance, or (EN 14126-B) and partial body protection (EN 13034 or EN 14605), or equivalent</p>	<p>• EU PPE Regulation 2016/425 and EU MDD Directive 93/42/EEC • FDA Class I or II medical device, or equivalent •WHO spec: [EN 13795 any performance level, or AAMI PB70 all levels acceptable, or equivalent] ISO 13688:2013, Protective clothing – General requirements ISO 8559-1:2017(en) Size designation of clothes — Part 1: Anthropometric definitions for body measurement</p>	<p>Option 1: fluid penetration resistant: EN 13795 high performance, or AAMI PB70 level 3 performance or above, or equivalent Option 2: blood borne pathogens penetration resistant: AAMI PB70 level 4 performance, or (EN 14126-B) and partial body protection (EN 13034 or EN 14605), or equivalent</p>	<p>SANS 53795, Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment - General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels</p>
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International standards

- EU PPE Regulation 2016/425 and EU MDD Directive 93/42/EEC
- FDA Class I or II medical device, or equivalent
- EN 13795 any performance level, or
- AAMI PB70 all levels acceptable, or equivalent

Local standards:

- SAHPRA medical Device Licence not needed for Class A devices
- SANS 53795



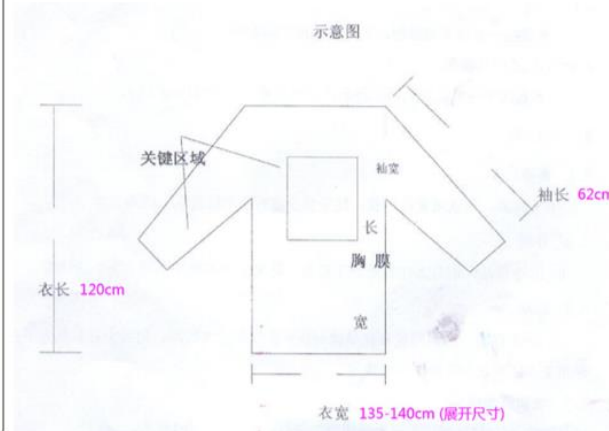
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DISPOSABLE GOWN GARMENT SPECIFICATION				
SIZING	RATIO	SEWING	INSTRUCTIONS	PACKING
M	40%	SLEEVE OPENING: Elasticated 18mm tunnel elastic	LABEL	Single pack in plastic bag
XL	60%	CLOSURE: Velcro back neck TIES / NECK: Self Fabric binding	Size label or print inside center back	Size table top RH corner 30 Units per outer carton

POM		M	XL
A	1/2 CHEST	69.5	79
B	1/2 HEM	69.5	79
C	SHOULDER	23	26
D	SHOULDER TO SHOULDER	70.5	77
E	CENTER BACK TO HEM	118	125
F	1/2 SLEEVE BICEP	29	30
G	INSIDE SLEEVE (UNDERARM)	68.5	69.5
H	SIDE SEAM	93.5	95
I	BACK NECK OPENING /NSP TO NSP	25.5	27
J	FRONT NECK DROP	9	9
K	1/2 SLEEVE OPENING	8	9
HEM		Raw edge	Raw edge
NECK BINDING		CUT 25MM	CUT 35MM
CUT ELASTIC		18	20
TIE LENGTH RIGTH BACK		61	61
TIE LENGTH LEFT BACK		44	44
TIE LENGTH RIGTH FRONT		39	39
TIE LENGTH LEFT FRONT		41	41



Sizes:

Small – 5%

Medium – 40%

Large – 40%

X-large – 15%

Lefapha la Dikgwebisano, Diintaseteri le Tlholisano • Lefapha la Kgwebo Indasteri le Phadišhano • uMnyango wezoHwebo neZimboni kanye noMncintiswano • Muhasho wa zwa Mbambadzo, Makwevho na Muṭaṭisano • Die Departement van Handel, Nywerheid en Mededinging • Kgoro ya Kgwebo Indasteri le Kgaisano • Ndzawulo ya Vuxavisi, Mabindzu na Mphikizano • Litiko leTekuhweba tiMboni neKuncintiswano • ISebe lezoRhwebo noShishino kunye noKhuphiswano • UmNyango wezokuRhwebelana, amaBubulo nama Phaliswano

