health
Department:
Health
REPUBLIC OF SOUTH AFRICA

2030 NDP

COVID-19 DISEASE: Personal protective equipment, body bags, disinfectants, alcohol-based hand rub and digital thermometers

Specification Guidelines

21 August 2020

Foreword

The World Health Organization (WHO) declared Covid-19 a global pandemic on 11th March 2020. The first case was diagnosed in South Africa on 5th March 2020. South Africa faces a particular challenge given the large vulnerable immunocompromised population living in overcrowded conditions.

This guideline provides guidance for developing tender specifications and procuring the required standard and quality of personal protective equipment (PPE), body bags, disinfectants, alcohol-based hand rub (ABHR) and thermometers for use during the Covid-19 pandemic. The list of PPE and disinfectants included in the guidance is according to the recommendations provided in the COVID-19 Disease: Infection Prevention and Control guidelines and therefore do not include the complete list of PPE and disinfectants. It is limited to the Covid-19 response and should not impact the routine procurement of PPE, body bags, ABHR, disinfectants, thermometers or similar products. It does not seek to replace "normal state" tender processes.

The specifications will give guidance to National Treasury for updating suggested product pricing. This should benefit the budget by reducing the number of products National Treasury needs to make emergency funds available for. Aligning prices with specifications will reduce the occurrence of over/under-paying for the products.

This guideline must be read in conjunction with the COVID-19 Disease: Infection Prevention and Control guidelines and the Practical Manual for the Implementation of the National Infection Prevention and Control Strategic Framework that provides further guidance regarding the appropriate and rational use of PPE, ABHR and disinfectants.

These guidelines will evolve as knowledge regarding strategies to address Covid-19 develop globally and in South Africa. These guidelines will therefore be updated based on emerging evidence and WHO recommendations.

Attention and reference are directed to the Preferential Procurement Policy Framework Act 5 of 2000 ("PPPFA") with specific reference to Regulation 8 (Local Production and Content) of the regulations gazetted 20 January 2017. Respirators (and the majority of PPE) are listed under "Clothing and Textiles" as a "Designated Product" for 100% local production and procurement. This means that all procurement of respirators is subject to the local content requirements of the Act and Regulation 8 of the Preferential Procurement Regulations of 2017. (Please see Appendix B for further details in this regard)

The specification list was developed through collaboration with several parties, from both private and public spheres. Reference documents used is existing tender and National Treasury specifications, IPC guidelines and WHO guidelines.

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I express special appreciation to the PPE Coordinators in provincial department of health who reviewed the guideline and provided insightful comments and direction.

Dr SSS Buthelezi

Director-General of Health Date:

Contents

1. PERSONAL PROTECTIVE EQUIPMENT

Product name	Sizes	NSN Number/ description	Description	International Standards	South African standards
Respirators (FFP2, N95, KN95)	Small, medium, large	Number: 222000994 (FFP2/ KN95) 222000993 (N95) Description: Mask respirator FFP2/ KN95 1'S OR Mask respirator N95 1'S	Medical, particulate filtering half mask: Disposable **Design requirements:** Description: Particulate filtration respirators used for protection against airborne diseases such as tuberculosis. FFP2 or N95 respirator, or higher Good breathability with a design that does not collapse against the mouth (e.g. duckbill, cup shaped). • A particulate filtration half mask must cover the chin, mouth and nose; it may/ may not have an exhalation valve. Note: non-valved respirators are recommended for the COVID 19 pandemic. • The particulate filtration respirator must not disintegrate during continuous or intermittent use in a 8 hour work day. • Parts of the particulate filtration respirator that are more likely to come into contact with the wearer must be hypo-allergenic. • Filter performance must meet standards relevant to the specific respirator classification. • The respirator must have an adjustable/self-adjustable head harness which ensures ease of donning or removal of the respirator. (Please note elastic ear loops are NOT appropriate) • The particulate filtration respirator must have a filtration efficiency of at least 94% for FFP2 respirators and 95% for N95 and KN95 respirators. • The particulate filtration respirator shall have the equivalent of an external hydrophobic fabric layer for droplet protection. • Specific lot and brand testing is mandatory. **Labelling Requirements:** 1. Name or trademark 2. Filter efficiency/Classification 3. Approval number 4. Standard compliance 5. Size of the respirator[1] A respirator mask, intended for use in a clinical environment, requires pre-approval from the NRCS. The manufacturer, distributor, or wholesaler of said mask, requires licensing approval from SAHPRA as a device establishment. Please read this specification in conjunction with the NDoH respirator quality assurance guideline, as more details are provided. [2]	• Minimum "FFP2 according to EN 149, EU PPE • Regulation 2016/425 Category III, or • Minimum "N95" respirator according to FDA Class II, under 21 CFR 878.4040, and CDC NIOSH, or equivalent ISO 16900-1, ISO 17420-1 and 2 ISO/TS 16976-8:2013, Respiratory protective devices — Human factors — Part 8: Ergonomic factors 42 CFR Part 84 Chinese PAHO standards According to EN 149 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking, three categories are listed as FFP1、FFP2 and FFP3, and the last two recognized as mainstream products. GB 2626 is similar to it	SANS 50149, Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking SANS 1866, Part 2: Medical respirators SANS 10220, Standard for selection, use and maintenance of respiratory PPE (Guidance standard not tested against) VC8072:2011, as published in Government Notice No. R. 407 (Government Gazette No. 34272) of 13 May 2011 **SAHPRA: Class B**
Fit Test Kit	One size		Kit includes: hood, collar, 2 nebulisers, sweet tasting sensitivity solution, sweet tasting fit test solution and laminated user instructions. [3]	Meets the performance criteria for fit testing respirators under the current OSHA Standard for Respirator Protection: 29 CFR 1910.134, Appendix A	

[1] National Treasury. Instruction No. 5 of 2020/21. April 2020
[2] Policy for the Regulation of Quality Respiratory Protective Equipment (RPE) Supply in Healthcare
[3] World Health Organization. COVID-19 PPE Specification Guidelines, Version 4.

Product name	Sizes	NSN Number/ description	Description	International Standards	South African standards
Surgical Mask	One size	Number: 222000992 Description: Surgical mask type 2, pleated, blue 1's	Surgical mask, good breathability; internal and external faces should be clearly identified Type II or higher. Fluid mask without eye shield, single use.[4] The mask should be made from three layers of fabric and pleated horizontally. Have ear loops (preferred) or four tie backs for fastening to head. Fit a wide range of face shapes and sizes to permit easy breathing. Have a nose piece of flexible material at the front which enables the mask to be shaped around the nose and face to ensure a secure fit and good seal. There can also be a strip of foam rubber at the top edge at the back (optional). **Packaging Requirements:** Bacterial filtration efficiency, latex content, classification and type. Box of 50[5] Please note: Currently due to constraints testing bacterial filtration efficiency within South Africa, SAHPRA may declare conditional exclusions of and modifications to the tests of SANS 1866-1:2018 for South African manufacturers.	• EU MDD Directive 93/42/EEC Category III or equivalent • EN 14683 Type II, IR, IIIR • ASTM F2100 minimum level 1 or equivalent ISO/TS 16976-8:2013, Respiratory protective devices — Human factors — Part 8: Ergonomic factors **Chinese PAHO standards** According to EN 14683 Surgical Masks— Requirements and test methods, surgical masks are classified into three types, TYPE I, TYPE II and TYPE IIR. TYPE II and TYPE IIR are applied to medical staff. The Chinese standards of YY 0469-2011 and YY/T 0969-2013 cover the classification and requirements described in EN 14683.	SANS 1866-1: 2018 Medical devices Part 1: Medical face masks SANS 1866:2008 (Provides alternative tests to the BFE test) SANS 50149:2003 **SAHPRA:** Class A Non- sterile – exclusion from SAHPRA licence

[4] National Treasury. Instruction No. 5 of 2020/21. April 2020

[5] Government Tender: Contract Number HM04-2015SS: Supply and Delivery of surgical sundries to the Department of Health. (http://www.health.gov.za/tender/docs/Adendum/HM042015SSAdd19.pdf)

Product name	Sizes	NSN Number/ description	Description	International Standards	South African standards
Gown: Cotton	Large/ Extra Large		**Material Requirements:** Fabric material: SABS 1401 Part I and IV Type P48. 100% Cotton and fully pre-shrunk Colour: Can be specified if preferred. **Design Requirements:** Style: The gown to have an over-lapping back, fastening at the side neck and waist, raglan sleeves with knitted autoclavable cuffs and a round neck. Lettering: The item can be marked, if preferred, with the province's abbreviated name, 20mm lettering black over the entire face of the item. Neck: Round neck, faced inside with self-material 4-6cm wide, scooped out to a depth of 6cm from the base of the throat or 17cm from the joint of the neck and shoulder seams. Neck edge and facing to be stitched down and threaded with 1.25cm wide tape, 145cm long for large gowns and 150cm long for extra-large gowns. The tape must be stitched fast in the centre front. Front: The front must be one piece of self-material. Width 76cm, length 150cm. Tapers to neckband with raglan sleeves and under-back. Under-back: The under-back shall be of self-material seamed (left back) on the left side. Shaped from the neck to the waist, tying at the right-side seam 18cm below the armhole by means of 60cm ties in the under-back left side seam and the right-side seams. The side edge shall be hemmed 1.25cm. From waist to hem width shall be 60cm. Outer-back: The outer-back shall be of self-material seamed (right back) at the right side and shaped from the neck to the waist. It shall tie at the neck. Tie at the waist by means of 60cm ties attached to the left side flap seam and the right-side seam and a tie 60cm inside this right seam. The side edge shall be hemmed 1.25cm from waist to hem with a width of 70cm for large gowns and 75cm for extra-large gowns. Sleeves: the sleeves shall be self-material, 2-piece raglan sleeves and shall have 10cm good autoclavable quality knitted cuffs or have thumb/finger loops to anchor sleeves in place.. Circumference of cuff un-stretched 18cm stretching to ±27cm Cuffs: Cuffs must be autoclavable Stitching: Thread M80 mercerised, stiches 5 per 10mm Seams: The bottom of the gown shall be hemmed 1.5cm. All seams must be double felled. All ties must be neat and securely bar tacked. **Dimension Requirements (Finished):** Chest - 160cm for large and 165cm for extra-large Bottom - width 165 for large and 170cm for extra-large Length – 150cm for large and 155cm for extra-large Neck circumference – 70cm for large and 75cm for extra-large Sleeve underarm – 75cm for large and 80cm for extra-large From neck to cuff – 80cm for large and 85cm for extra-large **Labelling Requirements:** Size tab: Mercerised and singed dye fast size tab to be sewn on each item indicating item no, size, manufacturer name, month and year (e.g. Feb 2020.[6]		SABS 1401 Part I and IV Type P.48. 100% Cotton and Fully pre-shrunk. **SAHPRA:** Class A Non- sterile – exclusion from SAHPRA licence
Gown: Reusable, water resistant	Large, extra Large		Reusable gown **Material Requirements:** Water resistant material to resist a minimum of 75 washes (40 Celsius wash and 60 Celsius dry). Gowns should have the same wearability as normal cotton (isolation) gowns. **Design Requirements:** Elastic cuff, tape-tab/velcro neck closure, Tie waist. **Dimension Requirements:** Length: (from shoulder to hem) 116cm for large and 127cm for extra-large Sleeve length: (from shoulder to wrist) 56cm for large and 62cm for extra-large Belt length: 167 for large and 172cm for extra-large Belt Width: 5cm Belt place: (neck to top of belt): 38cm for large and 39cm for extra-large[7]	ISO 16604 and ASTM 1671	SANS 53795 and ISO 5099 for water resistance **SAHPRA:** Class A Non- sterile – exclusion from SAHPRA licence

[6] KwaZulu-Natal Department of Health. Tender number ZNB 5770-2019 ver 1.2 for "Gown surgeon jade green" (http://www.kznhealth.gov.za/SCM/Advert/2020/June/210.2021.QN.pdf)
[7] Adapted from PrionTex specifications for reusable gowns.

Product name	Sizes	NSN Number/ description	Description	International Standards	South African standards
Gown: Disposable (isolation)	Large, extra Large	Number: 222000998 Description: Gowns - Isolation 1'S	**Material Requirements** Isolation gowns to be manufactured from protective fabrics with fluid-resistant properties. Possible materials include: a protective 3- layer SMS (Spunbond/Meltblown/Spunbond) polypropylene non-woven product, other alternatives are laminated, coated or calendered materials that comply with the performance criteria as indicated by the stipulated standards. **Design Requirements** Design criteria to be consistent for Isolation gowns. Elasticated cuff or thumb/finger loops to anchor sleeves in place, Tape-tab neck closure, Ties for waist. Where required, Purchasing authorities can specify alternatives for knitted cuffs or Velcro tabs for neck closures. **Dimension Requirements** Size to be clearly identified on the garment and packaging. Length: (from shoulder to hem) 116cm for large and 127cm for extra-large Sleeve length: (from shoulder to wrist) 56cm for large and 62cm for extra-large Belt length: 167 for large and 172cm for extra-large Belt Width: 5cm Belt position: (neck to top of belt): 38cm for large and 39cm for extra-large Colour: To be specified by Purchasing Authority- light colours preferable to better detect possible contamination.[8]	• EU PPE Regulation 2016/425 and EU MDD Directive 93/42/EEC • FDA Class I or II medical device, or equivalent •WHO spec: (AAMI PB70 all levels acceptable (Level 2 fluid penetration resistance = 20cm; Level 3 fluid penetration resistance = 50cm, or equivalent) ISO 13688:2013, Protective clothing – General requirements (Also provides information which must be specified on the order) EN 13795 – as adopted by SANS.	SANS 53795 as per standard performance (fluid penetration resistance = 20cm) 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 **SAHPRA:** Class A Non- sterile – exclusion from SAHPRA licence
Apron	One size: Cover entire front and sits high on chest	Number: 222000995 Description: Aprons 1's	**Material Requirements:** No-noise smooth waterproof plastic material **Design Requirements:** Apron, plastic, full body, single use/disposable, sleeveless. Adjustable waist tie. Fixed neck strap. Colour can be specified if preferred. Thickness: ≥25 micron **Dimension Requirements:** Ties length: not less than 50cm Width: not less than 5cm Each Covering size: 70-90 cm (width) X 120-150cm (height), or standard adult size.[9,10]	ISO 13688:2013(EN)	None **SAHPRA:** Class A Non- sterile – exclusion from SAHPRA licence
Gloves, examination, non-sterile, nitrile	Small, medium, large, extra large	Number: 222000987 (S) 222000988 (M) 222000989 (L) 222000987 (XL) Description: Examination gloves type 2 nitrile small/medium/ large/x-large 1's	**Material Requirements:** Nitrile, must be for single use, disposable, powder free, latex free, non-sterile and medical grade. **Design Requirements:** Glove examination. Gloves should have long cuffs, reaching well above the wrist, ideally to mid-forearm.[11] **Packaging Requirements:** Each individual box must be labeled with a Lot no. and Expiry date including the samples submitted for evaluation Where a product is lot controlled, there must be no more than two (2) lot numbers sent for independent analysis * Nitrile gloves are the preferred latex-free choice for health care workers who are allergic to latex.	• EU MDD Directive 93/42/EEC Category III • EU PPE Regulation 2016/425 Category III • EN 455 • EN 374 • ANSI/ISEA 105, • ASTM D6319, or equivalent	The Examination Nitrile Gloves must be SABS or ISO certified (SANS 11193-1:2010) for "Gloves made primarily from nitrile rubber latex, polychloroprene rubber latex, styrene-butadiene rubber solution, styrene-butadiene rubber emulsion or thermoplastic elastomer solution" **SAHPRA:** Class A Non- sterile – exclusion from SAHPRA licence

[8] KwaZulu-Natal Department of Health. Tender: ZNQ: 16/2020 Niem for "Isolation gown" (http://www.kznhealth.gov.za/SCM/Advert/2020/March/16.20.NIEM.pdf)
[9] National Treasury. Instruction No. 05 of 2020/21. April 2020
[10] National Department of Health. Tender: HM04-2015SS: Supply and delivery of surgical sundries to the Department of Health (http://www.health.gov.za/tender/docs/Adendum/HM042015SSAdd15.pdf)
[11] National Treasury Instruction NO. 05 of 2020/21. April 2020

Product name	Sizes	NSN Number/ description	Description	International Standards	South African standards
Gloves, examination, non-sterile, latex	Small, medium, large, extra large		Glove, Examination, non-sterile, Type 1(gloves made primarily from natural rubber latex). Glove shall be coloured for easy identification (excluding red colour) Powder free, For High risk use.[12] Textured surface and cut cuff, **Dimension Requirements:** Length: not less than 290mm, **Packaging Requirements:** Ambidextrous. Box of 50 gloves. Box must be labelled with a lot number and expiry date, including samples submitted for evaluation. Where a product is lot controlled, there must be no more than two (2) lot numbers sent for independent analysis. **Testing Requirements:** Report of the concentrations of allergenic proteins from an accredited laboratory clearly stating the test methods and the unit of measurement used must be supplied. It is recommended that the Fitkit method be used for analysis. Only gloves with the sum of concentration of hev b1, hev b3, hev b 5 and hev b 6.02 of 0.15µg/g or less or gloves with the sum of the 2 most important allergens in health care workers (hev b5 and hev b 6.02) of 0.05µg/g or less will be accepted. If concentrations of specific allergens are not available, total protein concentrations must be given. Details of the methods and the unit of measurements used should be given since these differ in different test methods.[13] The ASTM standard D6499 - the protein content of latex gloves should be below 50µg protein/g glove. TRGS - the protein content of latex gloves should be below 30µg protein /g glove.		Non-sterile gloves must comply with and be tested according to the test methodology provided in SANS11193-1:2010 "Single-use medical examination gloves Part 1: Specification for gloves made from rubber latex or rubber solution **SAHPRA:** Class A Non- sterile – exclusion from SAHPRA licence
Goggles	One size	Number: 222000996 Description: Goggles 1's	**Goggle frames:** Manufactured from Polypropylene or similar material that is pliable enough to seal against the facial contours and maintain rigidity to hold the lens securely in position, even under pressure. The grade of material used in the frame must not cause irritation or allergic reaction when in contact with the skin of the user and allows the penetration of light and vision through the frame. Direct Venting refers to openings/gaps on the frame to allow airflow to prevent lenses from fogging. Indirect Venting is achieved by designing the goggle frames to limit "direct airflow" (each manufacturer has its own method of achieving this). Indirect venting is preferred to prevent fogging. **Goggle lenses**: Manufactured from a transparent material with fog and scratch resistant treatment that allows one to see without allowing any droplets or liquids to pass through and/or enter. Must be clear with minimal tinting and provide a clear field of vision, be optically correct with no blemishes or inconsistencies in the lens or surfaces. The lenses must be securely mounted in the goggle frames and not easily dislodged by bumps or impact and to be manufactured from impact resistant clear grade polycarbonate or other compliant material. **Securing headband:** To be a minimum of 15mm width braided elastic to provide secure positioning of the goggle frame. After fitment and adjustment to the size and comfortable for extended periods for the wearer. Made from material that is sustainable and non-toxic and does not cause irritation to the user. **General:** Maybe re-usable (provided appropriate arrangements for decontamination are in place) or disposable. Users with glasses should rather use a face shield.[14]	• EU PPE Regulation 2016/425 • EN 166 • ANSI/ISEA Z87.1 or equivalent CE/FDA/ ANSI Z87.1	SANS 1404, Eye-protectors for industrial and non-industrial use SANS 50166 **SAHPRA** Class A Non- sterile – exclusion from SAHPRA licence

[12] National Treasury. Instruction No. 05 of 2020/21. April 2020.
[13] National Institute for Occupational Health. Input from Dr T Singh (full document available on request). July 2020.
[14] Cosmetics Chemical Pharmaceutical and Plastics Manufacturing Industry for General Public Use. Face Shield and Goggles: Recommended Guidelines Manufactured in the Republic of South Africa. Cosmetics Chemical Pharmaceutical and Plastics Manufacturing Industry for General Public Use. July 2020.

Product name	Sizes	NSN Number/ description	Description	International Standards	South African standards
Face Shield	Full facepiece length that extends to the bottom of the chin, Face/neck length that also covers the anterior neck area		**Visor (window/lense):** • **Material:** o Manufactured from polycarbonate, propionate, acetate, polyvinyl chloride, and polyethylene terephthalate glycol (PETG). Acetate provides the best clarity. Polycarbonate and propionate offer better, although still somewhat imperfect, the optical quality that aids in reducing eye strain associated with face shield wear. PETG is the most economical and manufactured locally, and therefore mostly used. Should be made with anti-fogging material properties. . • **Dimensions:** o Width - Sufficient width to reach at least the point of the ear, minimum 28cm. o Length - Full facepiece length that extends to the bottom of the chin (minimum length of 16cm measured from face shield band) OR Face/neck length that also covers the anterior neck area (minimum length of 20cm measured from face shield band). • Visors vary in lens thickness and generally the thinner the lens the more disposable the face shield is and thicker lenses of above 400um (micron) are the most reusable. • It can be disposable, reusable, or replaceable **Frame:** Manufactured from lightweight, smooth material like polypropylene plastic that is easy to clean and disinfect. Fully or partially encircle the circumference of the head. The headband should be ergonomic in design/material for comfort and durability of use. **Suspension system:** Suspension system to have either fully or partially circumferential attachment features. Fully circumferential suspension systems include plastic headbands that are adjustable for comfort by a ratchet mechanism, pin-lock systems, or Velcro; nonadjustable systems employ elastic straps. A top foam band or plastic injection-molded headpiece that is either fixed or adjusted for depth to ensure a snug fit against the forehead. There must be sufficient space between the visor and the face to wear spectacles and to breathe and talk comfortably.[15] Note: The frame and suspension system should not be 3D printed as the fibre groove lines do not allow for effective disinfection. **Labelling:** list of the materials used in its production, care and cleaning procedures and whether it is disposable or reusable. For disposable face shields, when to discard a face shield (when its functionality has been compromised and the number of washes/disinfection it can withstand). [16,17]	• EU PPE Regulation 2016/425 • EN 166 • ANSI/ISEA Z87.1 or equivalent ANSI Z87.1-2003 (occupational and educational eye and face protection) EU standard directive 86/686/EEC, EN 166/2002, ANSI/ISEA Z87.1-2010, or equivalent ISO	SANS 1404, Eye-protectors for industrial and non-industrial use amended test methods. SANS 50166 **SAHPRA** Class A Non- sterile – exclusion from SAHPRA licence
Long rubber utility cleaning glove	Small, medium, large		Can be washed; for cleaning staff. The outer glove should have long cuffs, reaching well above the wrist, ideally to mid-forearm, Minimum 280 mm total length. Reusable.[18]		Need a standard for reference
Heavy duty and heat-resistant gloves	One size		For removal of waste and use with Sterilisers in Sterile Services Department Leather and reinforced to protect against sharps, heat and chemicals.[19]	Puncture-resistant, FDA compliant	SANS 416, Chemical, heat resistant gloves

[15] Aurum Innova. Production specification. Medical face shields. April 2020

[16] F. Selcen Kilinc. (Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory). A Review of Isolation Gowns in Healthcare: Fabric and Gown Properties. J Eng Fiber Fabr. 10(3): 180–190. September 2016

[17] Cosmetics Chemical Pharmaceutical and Plastics Manufacturing Industry for General Public Use. Face Shield and Goggles: Recommended Guidelines Manufactured in the Republic of South Africa. Cosmetics Chemical Pharmaceutical and Plastics Manufacturing Industry for General Public Use. July 2020.

[18] National Department of Health. National Practical Manual for the Implementation of the National IPC Strategic Framework, March 2020, p 23. Available from: (http://www.health.gov.za/index.php/antimicrobial-resistance/category/629-infection-prevention-and-control-documents)

2. Body bags

Product name	Sizes	NSN Number/ description	Description	International Standards	South African standards
Body bags	Infant, Child, small, medium, Large, extra-large (XL), XXL, XXXL	Number: 222001012 Description: Body bag 1's	**Material Requirements:** The Body Bag is manufactured from ≥160 micron reinforced LLDPE or LDPE or 275 micron unsupported PVC (only to be considered when LLDPE and LDPE is not available as it is expensive), **Design Requirements:** Both ends are heat sealed and/or welded to prevent any leakage. There must be three (3) handles on each side using 38mm pebble webbing with a full length curved zip, all handles must be box stitched using Polycotton Corespun Polished 36 Tex thread, and box stitching dimensions are all 4cm x 3cm.[20] **Sizing Requirements:** Infant - 500mmx500 Child - 700mmx1m Small - 1.3mx1m Medium - 1.7mx1m Large - 2mx1m XL - 2.3x1m XXL - 2.6x1m XXXL - 2.9x1m	Made of linear enforced, U-shape zipper and 2 zipper pulls with tie ribs. Adult size 250x120cm Protector Body Bag specifications: 6 handles Impermeable, linear reinforced LLDPE and LDPE (avoid PVC as there is evidence that the toxin's it gives off while welding causes cancer), minimum thickness ≥160 microns;, Should contain no chlorides: burning of chlorides pollute the environment and can cause damage to retort chambers. Body bags should be non-carcinogenic to the health of funeral workers when used for cremations. At least 6 handles included in the body bag to allow burial team to hand carry it safely Heat-sealed: ensure superior strength and safety, Provide full containment of bloodborne pathogens Cracking point of 25 - 32 degrees below zero Shelf life: minimum of 10 years	The workmanship shall comply with the requirements for workmanship in specification SANS 1270 and All sewing shall be in accordance with SABS 10101. All heat welding shall be in accordance with SANS specifications. **SAHPRA** Class A Non- sterile – exclusion from SAHPRA licence

[19] National Department of Health. National Practical Manual for the Implementation of the National IPC Strategic Framework, March 2020, p 23. Available from: (http://www.health.gov.za/index.php/antimicrobial-resistance/category/629-infection-prevention-and-control-documents)
[20] National Treasury Instruction No. 05 of 2020/21. April 2020.

3. Disinfectants

Product name	Sizes	NSN Number/ description	Description	International Standards	South African standards
Alcohol for surface disinfection			Alcohol based cleaning solution for cleaning surfaces. ≥70% to 90% ethanol alcohol with NO emollient. [21]		SANS 1828 - Cleaning chemicals for use in the food industry SANS 1853 - Disinfectants, detergent-disinfectants and antiseptics for use in the food industry SANS 2231 - Bactericidal efficacy of alcohol-based products intended for general use. SANS 54885 - Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics **SAHPRA** Class B. requires license
Sanitizing/Disinfectant Wipes (Universal wipes)			Combined detergent and disinfectant. Peracetic acid and hydrogen peroxide or similar.[22]	EN1275, EN1276, EN13704, EN14348, EN14476, EN14561, EN14562 and EN14563.	SANS 1245 - Non-woven cleaning wipes **SAHPRA** Class B. requires license
Chlorine			Sodium dichloroisocyanurate **(NaDCC)** granules, , 60–70% + measurement spoon or NaDCC tablets. [23]		SANS 1032 - Detergent-disinfectants based on stabilized inorganic chlorine compounds. SANS 643 - Disinfectants based on stabilized inorganic chlorine compounds **SAHPRA** Class B. requires license

[21] National Department of Health. COVID-19 Disease: Infection Prevention and Control Guidelines. Version 2. May 2020
[22] National Department of Health. COVID-19 Disease: Infection Prevention and Control Guidelines. Version 2. May 2020
[23] National Department of Health. COVID-19 Disease: Infection Prevention and Control Guidelines. Version 2. May 2020

4. Alcohol-based hand rub

Product name	Sizes	NSN Number/ Description	Description	International Standards	South African standards
Alcohol-based hand rub (hand sanitiser)	500ml and 50ml Only consider 5l option if 500ml is out of stock as decanting is not recommended.		Alcohol Based hand rubs (Propyl, Isopropyl or Ethanol alcohol or a combination of these) with added emollient, in 50ml or 500ml bottle with plunger/mist spray top/flip top. Minimum standard: WHO I (Ethanol 85%, Glycerol 1.45%, Hydrogen peroxided 0.125%) or WHO II formulation (Isopropyl 75%,%, Glycerol 1.45%, Hydrogen peroxided 0.125%)).[24] EN testing passed for Hygienic Hand Rub (EN1500).[25]	https://apps.who.int/iris/bitstream/handle/10665/44102/9789241597906_eng.pdf?sequence=1 Chinese PAHO standards https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-guidance-production-alcohol-based-hand-sanitizer-help-boost	SANS 490 - Alcohol-based hand rub. SANS 1330 - Waterless hand cleaners **SAHPRA**: Requires medicine license (Please see SAPHRA exemption)

[24] WHO Recommended handrub formulations, WHO, 2009. Available at: https://www.who.int/gpsc/information_centre/handrub-formulations/en/
[25] National Department of Health. Contract HP11. 2020.

5. Digital Thermometers

Product name	Sizes	NSN Number/ description	Description	International Standards	South African standards
Digital Thermometer			The unit must: • Measure temporal artery temperature at least 4 cm away from the forehead • be suitable for all patients • measure temperature in °C • measurement range: 32 - 42°C • be able to take body temperature regardless of room temperature • be able to operate in high temperature up to 40 - 45°C • have a lab Accuracy: +/- 0,2°C • must provide reliable and stable results • display: LCD with backlight • be water resistant • self-test when switched on • have a low battery display • automatically shut off after 2 min of non-use • measure > 3000 measurements with one set of batteries • be hand-held, convenient and easy to use • be handed over in full operating order • have a starter-pack of consumables must be supplied with the unit • have 24-month warranty inclusive of corrective maintenance (Year 1 to Year 2) should be quoted for, as per the SCC document. **This is entails** A 2-year warranty against poor workmanship and latent defects and parts. This must be all inclusive and include, BUT NOT LIMITED TO, amongst others, ALL PARTS (including Batteries), Labour. The 2-year warranty must also include all quality checks, quality assurance requirements, Calibrations, Software updates and upgrades to be included.[26]	The unit must comply with an acceptable international electrical safety standard such as IEC 601-1 for medical equipment, attached certification	• OEM must comply and certified on ISO 9001 quality standards, attach proof of compliance • OEM must comply and certified on ISO 13485 quality standards, attach proof of compliance • **Model quoted must be CE certified. Attach a copy of the certification** **SAHPRA:** Class B (IR Contactless)

[26] National Department of Health: Directorate: Health Technology. July 2020.

6. Cloth masks

Product name	Sizes	Description	International Standards	South African standards
Cloth Mask		**Material Requirements:** • General Public Masks/Non-medical Masks (Cloth/Fabric Masks) can be made from a variety of woven and non-woven fabrics. • Fabrics made within the Republic of South Africa should be used for the manufacture of fabric/cloth face masks. • The objective of a fabric/cloth face mask is to act as a physical barrier to extremely small liquid droplets – the assumption being that the wearer/user is COVID-19 Positive and the intention is to hinder/stop the spread of the virus[27]. **Design Requirements:** • At least two layers of fabric is sufficient for balancing barrier efficiency, breathability and comfort - the fabric selection must ensure a comfort, barrier efficiency, breathability and duration of the use of a cloth mask. • An increase in the number of fabric layers will improve the barrier efficiency but may have the opposite effect on breathability and comfort. • Clear markings or design options must be used to distinguish between the outside of the mask and the inside of the mask. Construction should allow for the mask to sit halfway above the nose (on the nose bridge without obstructing vision or breathing functionality of the user), and halfway under the chin of the user, covering half of the face but leaving spaces open around the ears. • Cloth mask to tie behind the head, but can be easily modified by the wearer to tie behind the ears should that be a preference. • The mask is fully washable and reusable – fabric number of washes must be indicated • Non-toxic fabric and sustainability precautions must be adhered too.[28] **Packaging Requirements:** • Package must indicate size variation, taking cognisance of the Demographics of the Republic of South Africa's population. • A full set of instructions should be included with each pack Clear instruction for wear/use and cleaning of mask must come with packaging.	Please refer to the WHO site for their latest guidance: https://apps.who.int/iris/handle/10665/332293 At the time of the release of this guidance document, the most recent guidelines are from the 5th June 2020: https://apps.who.int/iris/bitstream/handle/10665/332293/WHO-2019-nCov-IPC_Masks-2020.4-eng.pdf?sequence=1&isAllowed=y	Currently, the DTIC's recommended Guidelines remains the applicable specification: http://www.thedtic.gov.za/wp-content/uploads/Updated_Recommended_Guidelines_Fabric_Face_Masks_May2020.pdf

[27] http://www.thedtic.gov.za/wp-content/uploads/Updated_Recommended_Guidelines_Fabric_Face_Masks_May2020.pdf

ANNEXURE A:
Policy for the Regulation of Quality Respiratory Protective Equipment (RPE) Supply in Healthcare

Please find this policy document shared along with these minimum specifications. The policy document on QA for RPE is critical for the procurement of safe, high quality respirators. The respirator specification provided in this minimum specifictions document should be read in conjunction with the Policy for the Regulation of Quality Respiratory Protective Equipment (RPE) Supply in Healthcare

ANNEXURE B:
Note from the Department of Trade Industry and Competition (DTIC)

"I call on every South African to remain strong and steadfast in these most difficult times. Stay safe and protect South Africa." [29]
President Matamela Cyril Ramaphosa, 01 August 2020

This specifications document has been adopted and adapted for the Republic of South Africa's demographics, taking into cognisance best practices and latest medical research to mitigate health care risks. In the procurement of medical products for the South African population and in response to Covid-19, the South African Specifications referenced in this document must be adhered to. The international standards made reference to in this document serve to assist and guide in referencing such foreign specifications.

In addition to adherence to latest medical research and best practices, it must be requested that in the procurement of medical products the Republic of South Africa's Re-imagined Industrial Strategy[30], Industrial Policy[31] and Procurement Legislation be given attention.

The central tenant of our Republic's re-imagined industrial strategy and policy is to address our triple challenges of poverty, inequality and unemployment. Within this context it is imperative that the procurement of medical products in response to Covid-19 (and in-general) should seek to support local manufacturers – the procurement (demand) of local manufactured goods/products (supply) has a net-positive impact on our country's socio-economic realties.

Within this context our Republic has enacted Legislation and Regulations that impose strict duties on public sector procurement: The Preferential Procurement Policy Framework Act 05[32] of 2000 (PPPFA) and the PPPFA Preferential Procurement Regulations[33], which came into effect on the 07 December 2011 empower the Department of Trade, Industry, and Competition (the dtic) to designate industries, sectors and sub-sectors for local production at a specified level of local content.

It must be noted that regulation 8(2) of the Preferential Procurement Regulations requires that organs of state to include local content in the invitation of bids and tenders. Regulation 8(5) states that if bids fail to meet the required local content such an application should not be acceptable. Further, local content rules require organs of state to populate Standard Bidding Documents 6. 2 (SBD 6.2) with a list of designated products and to circulate local content annexures.

Local content is applicable on goods designated for local production regardless on the procurement methods used by an organ of state. It is also applicable on turnkey projects where public money is spent and the project owned by the government.

The Designated Local Content information can be found here: http://www.thedtic.gov.za/sectors-and-services-2/industrial-development/industrial-procurement/

The dtic remains the custodian of the Designated Local Content legislation. The dtic may and can request all public entities to supply procurement information, especially information pertaining to adherence to local content legislation. Moreover, attention must also be given to the Judgement of 20 July 2020 in the High Court of South Africa, Gauteng Division Pretoria by Judge P. D. Phahlane in regard to Designated Local Content and procurement by organs of state. Judge Phahlane noted in the judgement that the dtic has discretionary power and is enabled by the PPPFA in enforcing policies of our government, particularly when ensuring procurement from local manufacturers using local materials within the Republic of South Africa.

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[29] http://www.treasury.gov.za/divisions/ocpo/sc/PPPFA/Preferential%20Procurement%20Policy%20Framework%20Act,%202000%20(Act%20No.5%20of%202000).pdf

[30] http://www.thedtic.gov.za/wp-content/uploads/Re-imagining-Industrial-Strategy-FINAL-13-June-2019.pdf

[31] http://www.thedtic.gov.za/wp-content/uploads/publication-IPAP.pdf

[32] http://www.treasury.gov.za/divisions/ocpo/sc/PPPFA/Preferential%20Procurement%20Policy%20Framework%20Act,%202000%20(Act%20No.5%20of%202000).pdf

[33] http://www.treasury.gov.za/divisions/ocpo/sc/PPPFA/1-34350%208-6%20NatTreas.pdf