PART 4: STATEMENT OF REQUIREMENTS.

HPVITS2024-194 Personal Protective Equipment (PPE).

Consolidated Category.

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PART 4: STATEMENT OF REQUIREMENTS

1. Participating Health Services

a. The Participating Health Services for this ITS (Invitation to Supply) are

i. All 'Public Health Services' (as legislatively defined) referred to in Schedule 1 and Schedule 5 of the *Health Services Act 1988*; and

ii. Other relevant participating health and health related organisations as follows:

- Eligible non-mandated health services

2. Scope

a. The scope of this ITS includes:

i. the supply of Drapes and Clinical Protective Apparel.

ii. the supply of Examination and Surgical Gloves products.

iii. the supply of Hand Hygiene & Chemical Disinfectant Products.

iv. Education and training.

3. Product Categories

a) A complete range of Personal Protective Equipment (PPE) is required for treatment of patients across Victorian Public Health Services

b) The categories required include:

CATEGORY NUMBER	CATEGORY NAME
1	Examination Gloves
2	Surgical Gloves
3	Glove Dispensers
4	Alcohol-Based Hand Rubs
5	Non-Medicated Hand Wash Solutions
6	Medicated Hand Wash Solutions
7	Moisturiser
8	Surface Cleaning Wipes
9	Chemical Surface Cleaners and Disinfectants

CATEGORY NUMBER	CATEGORY NAME
10	Food Service Chemicals
11	Washer Disinfector Chemicals
12	Laundry Chemicals
13	Reusable Medical Device Wipes
14	Accessories - Dispensers, Brackets, Pumps and Chemical Dispensers including Automated Chemical Dispensing and Dosing Systems (ACDDS)
15	Respiratory Protective Face Masks
16	Respirators
17	Eye and Face Protective Devices
18	Clinical Overshoes Cover
19	Headwear
20	Patient Underwear
21	Non-Sterile Single-Use Gowns for Patient Use
22	Single-Use Isolation Gowns
23	Single-Use Surgical/Procedure Gowns
24	Disposable Scrubs
25	Disposable Aprons
26	Disposable Antimicrobial Curtains and Screens
27	Adhesive Incise Drapes
28	Drapes
29	Drape Accessories
30	Equipment Covers

c) The Respondent may offer products in one, some or all categories.

d) HSV reserves the right not to consider any additional products offered.

e) For a full list of product categories and subcategories, refer to Appendix 1 - Product List.

4. Product Offering

a. Respondents are to list a direct match to the part and part number listed on the Response Worksheet.

b. If a direct match is not possible, list alternative or best match with the alternate part number.

c. HSV may not consider any product that is subject to a current HSV Agreement, other than those listed below:

   i. HPVC2015-051 Drapes and Clinical Protective Apparel.

   ii. HPVC2016-124 Hand Hygiene, Disinfectants and Chemical Products.

   iii. HPVC2019-019 Examination and Surgical Gloves.

d. Respondents will ensure that each product is offered in only one subcategory. It is the Respondent's responsibility to ensure that each product is submitted in the most appropriate subcategory.

5. Clinical Trials

a) Participating Health Services may, at their discretion, research or trial new technology or use non-contracted products to perform clinical trials at any time during the Term of any resulting Agreement.

Product Requirements

6. Standards and Compliance

a) All items offered must comply with relevant Australian Standards, Orders, Legislation and Regulations (collectively 'Compliance Requirements'), or their equivalent International Compliance Requirements. Refer to Appendix 2 – Compliance Requirements for a list of the minimum Compliance Requirements.

b) All therapeutic goods offered must be approved by the Australian Therapeutic Goods Administration (TGA), unless exempt. The Respondent must provide evidence of this (i.e. ARTG certificates) in its response. HSV recommends the use of products in accordance with TGA registered indications.

c) The successful Respondent must provide evidence of ARTG certification to Participating Health Services upon request.

7. Packaging and Labelling

a) Sterile products will be packaged in a manner that protects the contents from contamination during transportation, storage, and handling.

b) All labels must comply with the *Therapeutic Goods Act* 1989 and the *Therapeutic Goods (Medical Devices) Regulations* 2002.

c) Items will be delivered in accordance with the manufacturer's instructions.

8. Infection Control

(i) Where applicable, all items must meet the requirements of the Australian Guidelines for the Prevention and Control of Infection in Healthcare, Canberra: National Health and Medical Research Council (2019). Reusable medical devices (RMD) and agents for reprocessing RMD must meet the reprocessing standard of AS 5369:2023 Reprocessing of reusable medical devices and other devices in health and non-health related facilities.

(ii) Upon request by Participating Health Services, successful Respondents must provide reprocessing instructions for all reusable products within the Information for Use (IFU).

9. Substances of Concern

(i) Preference will be given to products (including their accompanying packaging) that are latex-free, unless otherwise stated.

(ii) Preference will be given to products that are free of diethylhexyl phthalate (DEHP).

10. Product Information

a) The Respondent will submit a copy of relevant product diagrams, specifications, or brochures to assist in accurately identifying products offered.

b) Where research papers or relevant scientific information is available, this should be submitted with the Response.

c) The level of protection is not mandated by the colour of the consumables.

d) All product information submitted should:

   (i) be in electronic format.

   (ii) be in English.

   (iii) be specific to the product offered.

   (iv) contain the Respondent's company name.

   (v) include the product code.

   (vi) include a detailed specification of the product.

   (vii) include clear diagrams/pictures of the product.

e) To assist in managing this material, all product information submitted should be labelled with the relevant HSV category and subcategory number.

f) Electronic copies should include the HSV Category and subcategory numbers in the filename or identifying metadata.

g) HSV may not consider unlabelled submissions.

h) Product information will not be evaluated but is necessary to assist in accurately identifying products offered.

i) HSV reserves the right to exclude products from evaluation when the product is unidentifiable and provided information is:

(i) Not labelled as per clause d above; or

i. Is incomplete as to clause c.

j) Product samples are not to be provided unless specifically requested by HSV, as per Part 2 clause **Error! Bookmark not defined.**.

k) The Respondent should not submit information relating to products that are not called for in this ITS.

11. Consignment Stock

a) Respondents should indicate whether it is providing any of the Deliverables on a consignment basis.

b) Respondents should nominate a Representative to undertake consignment duties.

c) Terms relating to Consignment Stock are set out under **Error! Reference source not found.** Consignment Stock and/or under any relevant Service Level Agreement.

12. Bracket/Dispensers/Pumps Arrangements

a) Respondents must advise the availability of free on loan Brackets/ Dispensers/ Pumps to support the storage and use of relevant PPE in their response.

13. Warranty

a) All products covered in this ITS are to be issued with a warranty of at least twelve (12) months from the delivery date for normal use.

b) Upon request, the successful Respondent will provide information (printed or electronic) explaining product warranty.

c) The repair or replacement of any item under warranty will be at no cost to the Participating Health Service.

d) The cost of any pickup or delivery associated with a repair or replacement under warranty will be borne by the successful Respondent.

e) It is highly desirable that the successful Respondent provides Participating Health Services with a replacement or suitable loan item at no cost until the repaired item is returned.

14. Recall Process

a) All recalls must be managed in line with the *Uniform Recall Procedure for Therapeutic Goods* (URPTG) (V2.2, December 2019).

b) All recalls and/or hazard alerts are to be completed using GS1 Recall OR Recall Health.

c) Class 1 recalls (as defined by the TGA's *Uniform Recall Procedure for Therapeutic Goods* (URPTG) (V2.3, June 2022) must also meet the requirements under section Part 5 on Warranty, where applicable.

Pricing

15. Price Variation

a) Price variation (if any) will be set out in and must be in accordance with **Error! Reference source not found.**.

16. Sole and Panel Pricing

a) HSV may choose to award a single supplier for this ITS (Sole Supply) or a panel of suppliers (Panel Supply).

b) In the Tender Response Worksheet, Respondents are to list price options for both Sole Supply and Panel Supply. Note sole supply ensures all contracted purchases by health services for a subcategory the subject of a sole supply award.

c) Where HSV elects to award panel supply, health services may choose to purchase from any or all contracted suppliers.

17. Price review

a) Price review (if any) will be set out in and must be in accordance with **Error! Reference source not found.**.

b) HSV reserves the right to negotiate price review outcomes with the successful Respondent.

Delivery

18. Electronic Data Interchange

a) The Participating Health Services prefer to exchange orders, payments, acknowledgements, invoices, remittance notices and other records (Data) electronically, in place of tangible documents. Successful Respondents are required to work with the Participating Health Services to achieve this outcome.

19. Delivery

a) HPVITS2024-194 Personal Protective Equipment (PPE) will be delivered to the location(s) specified by Participating Health Services within the shortest possible timeframe; however, this shall not exceed two (2) Business Days for metro Health Services and three (3) to four (4) Business Days for regional Health Services from receipt of order unless otherwise agreed with the Participating Health Service. Purchase Order processing and dispatching however must occur within 24 hours for both metro and regional Health Services.

20. Urgent Deliveries

a) For the purposes of this section, urgent deliveries refer to urgent requests placed by an individual Participating Health Service and does not include emergency situations.

b) The Respondent shall be able to receive and action urgent delivery requests 24 hours a day, 7 days a week.

c) Urgent deliveries should be received by Participating Health Services within 24 hours from receipt of order.

d) Any additional costs associated with Urgent Deliveries shall be clearly outlined in the User Guide tab of the Tender Response Worksheet and shall be discussed and agreed with the ordering health service prior to acceptance of any urgent order.

Support

21. Training

a) Upon request by a Participating Health Service, successful Respondents will deliver a training package and/or training materials to facilitate the introduction of their ITS to clinicians in their working environment.

b) Training requirements may include (but are not limited to):

(i) face-to-face training at Participating Health Service sites (i.e. in-service training)

(ii) off-site study days for clinicians

(iii) updates and refresher training on new products and/or equipment and surgical techniques

(iv) training on reprocessing for nominated personnel and the Participating Health Services' CSSD (Central Sterile Supply Department) and SSU (Sterile Supply Unit)

(v) training materials.

(vi) online Webinars

22. Customer Service and Support

a) The successful Respondent must be able to provide customer service and support to Participating Health Services, either directly or via a third party, during business hours

b) The successful Respondent will provide Participating Health Services with representatives that are:

(i) inherently familiar with the contracted products

(ii) appropriately qualified

(iii) technically/clinically knowledgeable about the contracted products

(iv) available to respond to Participating Health Services' queries during business hours.

c) It is desirable that nominated Representatives have a clinical background or experience.

d) The level of customer service and support required of Representatives is expected to include (but is not limited to):

   (i) liaising with clinicians to recommend products and solutions.

   (ii) promptly answering clinicians' queries (including after hours)

   (iii) liaising with various hospital departments (for example: operating theatre, Nurse Unit Managers)

   (iv) providing on-site clinical support during cases (if requested)

   (v) providing informational materials

   (vi) providing education and in-service training upon request.

e) Representatives must comply with Participating Health Services' local policies regarding engagement with Participating Health Service staff.

Award

23. Conditional Acceptance

a) Products may be designated as 'Conditionally Accepted' where products contain incomplete information as determined by HSV.

b) Clause 7.11 of the Draft Agreement sets out terms relating to Conditionally Accepted Deliverables.

c) Products designated as 'Conditionally Accepted' may be subject to desktop and clinical evaluation by health services.

d) "Acceptance for use" is confirmed by issuing a product acceptance certificate or any other form signed by an appropriate clinical representative of a Participating Health Service

e) Pricing will be as per response position and cannot be amended post Agreement acceptance.

24. Key Performance Indicators

a) Refer to **Error! Reference source not found.**.

25. Service Level Agreement

a) Participating Health Services may enter into a Service Level Agreement (SLA) with the successful Respondent(s), on the terms set out in the Draft Agreement clause 4.3 Service Level Agreement. The SLA may cover the following arrangements:

   (i) the provision of products on consignment

   (ii) requirements for stock management and rotation

   (iii) arrangements for ordering, invoicing, and delivery

(iv) social procurement commitments or framework set out by a Participating Health Service that may be linked to the Social Procurement Framework set out in the Agreement; and / or

(v) clinical support, including attendance requirements for Representatives in relation to education and training.

(vi) communication arrangements for product recalls and safety alerts (refer to PART 4: STATEMENT OF REQUIREMENTS clause 1414).

b) The SLA will be in addition to the Agreement between the successful Respondent(s) and HSV and will not alter any terms of the Agreement. Any SLA entered into between the Supplier and a Participating Health Service must be established in accordance with the framework of the Agreement and must not contravene or undermine the terms of the Agreement.

c) HSV will not be responsible for monitoring compliance with any SLA. This is a matter of agreement between the parties to the SLA.

d) Successful Respondent(s) will provide a copy of all Service Level Agreements to HSV within 1 week of being finalised.

Statement of Requirements (SOR)

The following document includes the statement of requirements for PPE categories. The document is split into three major areas including:

- Drapes & Clinical Protective Apparel
- Examination and Surgical Gloves
- Hand Hygiene & Chemical Disinfectant Products

The document only includes specification of products and categories for each PPE category.

Examination & Surgical Gloves

a. Tenderers must provide the following information in the product description of the Tender Response Worksheet, including:
   (i) Brand Name
   (ii) Material
   (iii) Size
   (iv) Colour
   (v) Sterile or non-sterile
   (vi) Single use
   (vii) Biodegradability
   (viii) Compliance to Standards, Orders, Legislations and Regulations as outlined in Appendix 1

b. Mandatory Criteria
   (i) Cuff bead
   (ii) External Finish
   (iii) Cytotoxic Drugs
      i. Where gloves are claimed to be recommended for use during the preparation and administration of cytotoxic drugs, Tenderers shall advise:
         - Treatments or processes that the glove has undergone during the manufacturing process to support this claim.
         - Independent testing data to support these claims.
         - This information shall also be made available to hospitals/health services upon request.
   (iv) When worn in accordance with manufacturer's instructions, gloves recommended for use during the preparation and administration of cytotoxic drugs shall provide protection against commonly used cytotoxic agents.
   (v) Gloves recommended for use during preparation and administration of cytotoxic drugs shall be of sufficient length to cover the cuffs of gowns or coveralls worn by the operator.

c. Additional Information

1. Category 1 – Examination Gloves

(i) Glove is safe for food preparation (HACCP Food Safety Standard)

2. Category 2 – Surgical Gloves

(i) Whether the glove is an under (indicator) glove, over glove, or combination glove.

3. Category 3 – Glove Dispensers

(i) Constructed so that difficult-to-clean corners are minimized.

(ii) Non-porous, smooth, and capable of being easily cleaned.

(iii) Sufficiently robust to withstand normal wear and tear.

(iv) Wall mountable dispensers shall be capable of being affixed to the wall in a robust manner that meets infection control requirements.

(v) Information regarding cleaning and disinfection requirements for reusable hardware items must be provided against Australian tested cleaning agents.

(vi) Wall mountable or other (e.g., bench top, trolley)

(vii) Method of fixation (where applicable)

(viii) The process and cost associated with the removal and disposal of old dispensers and fitting of new dispensers (including wall restorations) will be negotiated between the health service and supplier.

(ix) For free on loan arrangement, the cost of the dispensers must not be factored into the pricing of gloves.

Appendix 1 - Compliance Requirements

A2. Standards

Australian Standards, Orders, Legislation and Regulations

i. It is the responsibility of the Respondent to ensure that all products offered comply with the Compliance Requirements listed below. This is not an exhaustive list, Respondents must ensure they comply with any other Compliance Requirements that are not listed below, this includes primary and subordinate instruments of the State and Commonwealth, and any relevant amendments, revisions, or consolidations.

ii. The relevant legislation for HSVITS2024-194 may include, but is not limited to:

STANDARD NUMBER	STANDARD NAME
ISO 10282:2023	Single-use sterile rubber surgical gloves – Specification
ISO 11193-1:2020	Single-use medical examination gloves - Part 1: Specification for gloves made from rubber latex or rubber solution
ISO 374:2016	Protective gloves against dangerous chemicals and microorganisms
AS/NZS 2161.10.3:2005	Protective gloves against chemicals and micro-organisms – Determination of resistance to permeation by chemicals
AS/NZS 4011.1:2014	Single-use examination gloves Part 1: Specification for gloves made from rubber latex or rubber solution (ISO 11193-1:2008, MOD)
AS/NZS 4011:2:2014	Single –use medical examination gloves – Part 2: Specification for gloves made from poly (vinyl chloride) (ISO 11193-2:2006, MOD)
AS/NZS 4179:2014	Single-use sterile surgical rubber gloves – Specification (ISO 10282:2014, MOD)
ASTM D3577-19:2023	Standard Specification for Rubber Surgical Gloves
ASTM D3578-19:2023	Standard Specification for Rubber Examination Gloves
ASTM 6978-05:2023	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
ASTM D6319-2019: R2023	Standard Specification for Nitrile examination Gloves for Medical application
AS 5369:2023	Reprocessing of reusable medical devices and other devices in health and non-health related facilities

In addition, all Examination and Surgical Gloves offered shall comply with the following (where applicable):

- Occupational Health and Safety Act 2004
- ACORN Standards 16th edition.
- EVIQ, Safe handling and waste management of hazardous drugs, 2022

In addition, it is preferable the examination gloves also meet the following requirements:

i. HACCP Food Safe Certification

ii. These certificates of compliance shall also be provided in electronic form upon request from hospitals/health services.

A2. Legislation

(i) The references to the below legislation include any amendments, revisions, or consolidations to those references.

a. *Therapeutic Goods (Medical Devices) Regulations* 2002

b. *Therapeutic Goods Act* 1989

A2. Guidelines and Other References

(i) The references to the below guidelines include any amendments, revisions, or consolidations to those guidelines.

a. Australian Guidelines for the Prevention and Control of Infection in Healthcare, Canberra: National Health and Medical Research Council (2019)

b. Uniform Recall Procedure for Therapeutic Goods (URPTG) (V2.3, June 2022). Therapeutic Goods Administration (2011), Australian Regulatory Guidelines for Medical Devices

Hand Hygiene & Chemical Disinfectant Products

a. Tenderers must provide the following information in the product description of the Tender Response Worksheet, including.

b. Generic Information of the Product

(i) Brand Name
(ii) Material
(iii) Size
(iv) Dimensions / Volume / Weight
(v) Colour
(vi) Active ingredients
(vii) pH
(viii) Fragrance
(ix) Sterile or non-sterile
(x) Single use or re-usable
(xi) Biodegradability (Y/N)
(xii) Compliance to Standards, Orders, Legislations and Regulations as outlined in Appendix 2
(xiii) Product Information that is applicable to the categories of Hand Hygiene and Wipes

c. Hand Hygiene products and Cleaning Wipes

(i) Type
(ii) Other ingredients
(iii) Presentation
(iv) The form of solution e.g.: liquid, foam, gel, mist, spray etc.
(v) Type of available antiseptic (where applicable)
(vi) Percentage of available antiseptic (where applicable)
(vii) Type of emollient in the handrub (where applicable)
(viii) Percentage of emollient in the handrub
(ix) Type of hypoallergenic ingredient to minimise occupational dermatitis (where applicable)
(x) Effective dose based on the product usage instruction label.
(xi) Cost per dispensed dose on the product usage instruction label
(xii) Where a range of dispensed amounts is specified on the label, the minimum amount will be used for product evaluation.
(xiii) Type of dispensing mechanism e.g., flip cap, dispenser with lever, push pump.
(xiv) Accessories to be used with the product e.g., dispensers, brackets, or pumps.
(xv) Compatible with active ingredients in Medicated Hand Wash Solutions and Alcohol based hand rubs e.g.: Chlorhexidine, Iodine, Triclosan, so as not to deactivate these chemicals,
(xvi) Product Information that is applicable to the categories of Hand Hygiene and Wipes

d. Chemical Cleaners and Disinfectants

(i) Type of Dispenser e.g., Dosing system, pump
(ii) Type of cap
(iii) Cost of diluted solution per litre (that is; the ready to use or made up (mixed) solution based on the product mixing instructions label)
(iv) Where a range of product mixing instructions are specified on the label, the minimum amount will be used for product evaluation.
(v) For any additional components offered, Respondents shall provide a clear description of the component in the Product Description of the Tender Response Worksheet.

(vi) For all additional components offered, Respondents shall advise in the relevant column of the Tender Response Worksheet the product code/s with which the component is compatible.

(vii) Volatile Organic Compound (VOC) content (% w/w), undiluted

(viii) Provide a MSDS sheet with a list of all ingredients including but not limited to:

- Phosphates
- Chlorine
- Ammonia
- Quaternary ammonium salts
- If the product is listed as either a Hazardous Substance or Dangerous Good – (inclusive of Class 8 products)
- Shelf-life post dilution in hours (where applicable).

e. Additional Specifications to the individual category

1 Category 4 – Alcohol Based Hand Rubs

1.1 specialised hand rubs for surgery

1.2 needs to be a minimum of 70% (v/v) Alcohol.

1.3 heat and/or light resistant covers or similar to support effective product use where applicable to the product.

1.4 Where a pump mechanism is used for dispensing, a new pump is to be provided for each bottle of solution.

1.5 Unit packaging shall be labelled with instructions for loading hand rubs into the dispensers.

2 Category 5 – Non-medicated handwash solutions

2.1 Solution containers for wall-mounted dispensers shall form a closed system and shall not be capable of being refilled.

2.2 Where a pump mechanism is used for dispensing, a new pump shall be provided for each bottle of solution.

2.3 Unit packaging shall be labelled with instructions for loading hand wash solutions into the dispensers.

3 Category 6 – Medicated Hand Wash Solutions

3.1 Solution containers for wall-mounted dispensers shall form a closed system and shall not be capable of being re-filled.

3.2 Where a pump mechanism is used for dispensing, a new pump shall be provided for each bottle of solution.

3.3 Unit packaging shall be labelled with instructions for loading hand wash solutions into the dispensers.

4 Category 7 – Moisturiser

4.1 Moisturiser solutions are to be compatible with the range of hand hygiene products offered in Categories 4, 5 and 6.

4.2 Moisturiser solutions are to be water based.

4.3 Solution containers for wall-mounted dispensers shall form a closed system and shall not be capable of being refilled.

4.4 Where a pump mechanism is used for dispensing, a new pump shall be provided for each bottle of solution.

4.5 Unit packaging shall be labelled with instructions for loading moisturiser solutions into the dispensers.

5 Category 8 – Surface Cleaning Wipes

5.1 All Wipes shall be packaged in a resealable container to minimise the evaporation of the active ingredient or any other ingredient.

5.2 Preference may be given to wipes that have easy to read and clear set up instructions, are easy to open and set up, are easy to dispense sheets and have sheets that separate easily without wastage. Easy to open and set up includes ease of opening the tub or canister and ease of opening the inner sealed package if present (easy to tear apart, contains perforations, requires scissors etc).

5.3 Respondents are to indicate if products are effective against specific microorganism groups such as fungicides, sporicides, tuberculocides or virucide. Respondents shall supply documentary evidence as an attachment for review, in relation to the efficacy of such specific claims.

6 Category 9 – Chemical Surface Cleaners and Disinfectants

6.1 Most concentrated dilution factor recommended for end-use.

6.2 Disinfectants with specific claims in healthcare or healthcare related applications are to be 'listed' Therapeutic Goods with the TGA

6.3 Automated dosing systems – see Category 14: Manual systems and Automated Chemical Dispensing and Dosing System (ACDDS)

6.4 Glass cleaners shall evaporate quickly and be non–streaking.

6.5 Hard floor sealers shall be non-slip and able to be used with buffing machines.

6.6 All floor polish shall be quick drying, low residue, and non-slip.

6.7 Respondents, please note that Chemical Cleaners specifically designed for use in food service areas shall be tendered under Category 10: Food Service and Utility Washer Chemicals.

~~7~~ Category 10 – Food Service Chemicals

7.1 Only enzymatic or food grade products are to be tendered in this category.

7.2 Automated dosing systems – see Category 14: Manual systems and Automated Chemical Dispensing and Dosing System (ACDDS)

8 Category 11 – Washer Disinfector Chemicals

8.1 Respondents are to indicate if their chemicals are intended for use in Washer Disinfector's, Pan Sanitisers or in Combination machines/both.

8.2 IFU should state the intended use of the chemical and its compatibility with the intended medical device.

8.3 IFU should state compatibility with other washer disinfector cleaning agents.

8.4 IFU should state compatibility with washer disinfector machine materials i.e. Aluminium.

9 Category 12 – Laundry Chemicals

9.1 Where a range of dispensed amounts is specified on the label, the minimum amount will be used for product evaluation.

10 Category 13 – Reusable Medical Devices Wipes

10.1 A range of reusable medical device wipes, including cleaning wipes, disinfectant wipes (low-level, intermediate, or high-level disinfection).

11 Category 14 – Accessories- Dispensers, Brackets, Pumps and Chemical Dispensers including Automated Chemical Dispensing and Dosing Systems (ACDDS)

11.1 Accessories include Dispensers, Brackets, Pumps and Chemical Dispensers including Automated Chemical Dispensing and Dosing System (ACDDS) for the dispensing of product.

11.2 Accessories are required for the dispensing of hand hygiene, wipes, disinfectants, and chemical products to meet hospital needs for product use, product replacement, transitioning, rationalisation or upgrading of current systems.

11.3 Dispensers and Brackets

11.3.1 Dispensers can be wall mounted and be either operated by a lever or have an automatic mechanism.

11.3.2 Brackets can either be wall mounted or fixed to a structure or are attached to equipment such as a bed, trolley or are attached to clothing or a belt.

11.3.3 Dispenser and Brackets for Wipes includes any accessory that is associated with the wipes product but does not include the container that holds/contains the wipes.

11.3.4 Dispensers and brackets shall:

11.3.4.1 be robust and easy to clean.

11.3.4.2 have no rough or sharp edges.

11.3.5 For dispensers that have an automatic battery powered mechanism Respondents are to detail the battery life and change over services to health services.

11.3.6 When installed in a dispenser, the dispensing nozzle of each refill shall be shielded to minimise the risk of contamination.

11.3.7 Preference may be given to dispensers that have tamper proof properties and/or have a mechanism that reduces possible theft of the product.

11.3.8 Dispensers are to only have replaceable refills. Dispensers that have refillable containers will not be considered in this tender.

11.3.9 Respondents are to detail their installation plan in terms of how they would work with a health service, audit the number of existing accessory locations and new accessory locations, and minimise the time of changeover and impact on health services. This is to include how dispensers and brackets are to be removed and attached to walls or structures (adhesive, screwed, other) and how the restoration of surfaces and surrounds will be achieved. The plan is to also provide recommendations on safe distances from electrical points and other hazards and any other recommendation or process.

11.3.10 Respondents shall provide in the Tender Response Worksheet separated pricing for:

11.3.10.1 The price for each product in categories 4 to 13 of the TRW, based on the volume estimates in the TRW.

11.3.10.2 Pricing for dispensers and brackets (accessories) in category 14 of the TRW for the purchase and installation of dispensers and brackets. Respondents are to include the price or state in the TRW for each dispenser or bracket if there is zero cost. This includes installing new dispensers/brackets or replacing the current dispenser/brackets. Pricing is to be expressed per dispenser/bracket and include pricing for the volume ranges in the TRW.

11.3.10.3 Price for the provision of additional accessories during the contract as a result of breakage or new locations, or to indicate if the accessories are offered at ‘no cost’.

11.3.11 Respondents shall provide the following information on the Tender Response Worksheet:

11.3.11.1 whether it is possible to lock the dispenser

11.3.11.2 whether the dispenser or bracket is hand, elbow, or foot operated.

11.4 Container Pumps

11.4.1 Pumps are manually operated devices such as push pumps, push down nozzles and trigger sprays that fit onto a product container.

11.4.2 Pumps shall be sufficiently robust to retain their effective structure and function throughout use of an entire container.

11.4.3 Pumps shall be easy to use as a one-handed operation (where applicable).

11.4.4 Pumps shall have a smooth operation throughout the full use (full life) of the product.

11.4.5 Preference may be given to products with the pump either attached to each product container or contained within the packaging at time of delivery.

11.4.6 Preference may be given to pumps (and containers) that have tamper proof properties and/or mechanisms to reduce misuse (e.g.: in high-risk clinical areas).

11.4.7 Respondents shall provide in the Tender Response Worksheet pricing for:

11.4.7.1 the price for the pump if not included with the product.

11.4.7.2 costs associated with the provision of additional pumps, or if additional pumps are offered at 'no cost'.

12 27.4.10 Chemical Dispensers including Automated Chemical Dispensing and Dosing Systems (ACDDS)

12.1 Manual Chemical Dispensers and Brackets

12.1.1 All manual dispensers and/or brackets shall be provided free on loan and installed free of charge.

12.1.2 Respondents shall advise if a manual dispenser and/or bracket fitting service is available. Where a fitting service is available, Respondents shall provide the following information:

12.1.2.1 All costs associated with this service.

12.1.2.2 Whether this service includes removal and disposal of existing dispensers and/or brackets and the restoration of surfaces and painting of surrounds.

12.1.2.3 The resources available to undertake this process.

12.1.2.4 Use of any third-party subcontractors (including their relevant licences, such as electrical or plumbing licences)

12.1.2.5 The details and processes for repair/ replacement of any damaged or faulty dispensers and/or brackets

12.1.2.6 Ability to comply with specific health service requirements for:

- Contractor induction process (e.g., iPro LIVE)
- Engineering requirements in accordance with the National Construction Code.

12.1.3 Successful Respondents shall ensure that any third-party subcontractors comply with the requirements to have a valid Police Check and that they may be required to have a Working with Children Check

12.1.4 When installed in a dispenser, the dispensing nozzle of each refill shall be shielded to minimise the risk of contamination.

12.1.5 Manual dispensers and brackets shall:

12.1.5.1 Be robust and easy to clean.

12.1.5.2 Have no rough or sharp edges.

12.1.6 Manual dispensers that can be refilled with solutions may not be considered.

12.2 Automated Chemical Dispensing Dosing Systems (ACDDS)

12.2.1 ACDDS shall be provided free on loan and installed free of charge.

12.3 Functionality

12.3.1 Where an ACDDS is offered, Respondents shall advise the functional characteristics of the dispensing system, including but not limited to:

12.3.1.1 The type of system/s available (e.g., manual, or automated, portable, or permanent)

12.3.1.2 Functionality (e.g., closed loop)

12.3.1.3 Whether it is tamperproof

12.3.1.4 The range of system models available (e.g., bucket fill, bottle fill)

12.3.1.5 Physical dimensions in centimetres.

12.3.2 All ACDDS shall include an air gap or non-return valve compliant with the relevant Australian Plumbing Standards and/or Building Codes. Evidence of compliance shall be available to health services upon request.

12.3.3 Respondents are to indicate and provide details regarding if the ACDDS can incorporate a telemetry system to automate the tracking of chemical levels and re-ordering of liquid chemical stock.

12.4 Installation, Service and Maintenance

12.4.1 Respondents shall advise if an installation service is available. Where an installation service is available, Respondents will provide the following information:

12.4.1.1 Whether this service includes removal and disposal of existing dispensers and/or brackets and restoration of surfaces

12.4.1.2 The resources available to undertake this process.

12.4.1.3 Use of any third-party subcontractors (including their relevant licences, such as electrical or plumbing licences)

12.4.1.4 Ability to comply with specific health service requirements for:

- Contractor induction process (e.g., iPro LIVE)
- Engineering requirements in accordance with the National Construction Code.

12.4.2 Successful Respondents shall ensure that any third-party subcontractors comply with the requirements to have a valid Police Check and that they may be required to have a Working with Children Check

12.4.3 Servicing and maintenance shall include, but is not limited to:

12.4.3.1 Calibration

12.4.3.2 Dilution rate testing

12.4.3.3 Reporting of the above to the health service

12.4.3.4 Surface testing for infection control and food safety.

12.4.4 Respondents shall advise the frequency and content of service and maintenance which they will undertake on any ACDDS supplied under the Agreement to ensure continued compliance with all the relevant Australian Standards.

12.4.5 Documentary evidence of service and maintenance undertaken (e.g., a detailed service report) is to be provided at the time of each service to the health service's Building Engineering and Maintenance Services and/or as nominated by the health service. Respondents shall submit a pro forma of the proposed service report.

12.4.6 Respondents shall advise the details and processes for repair/replacement of any damaged or faulty ACDDS.

f. Transition In and Out Plan

(i) Respondents shall provide a transition plan that identifies how, if successful, they would undertake the transition of:

- A current user to the new contractual arrangement

- A new user to the Respondent's contracted range
- An existing user out of the current contractual arrangement.

(ii) This transition plan for both Manual Dispenser and Brackets and ACDDS shall include:

(iii) Details of the Respondent's ability to:

- Supply
- Install
- Remove

(iv) A risk assessment and mitigation plan (e.g., alternatives where water pressure is not suitable)

(v) A detailed project plan that includes:

- Any minimum lead-times
- Timelines
- Resourcing (including on behalf of the health service, successful Respondent, and any third-party suppliers/subcontractors)
- Contingency plan

(vi) Identification of a hospital or health service's product requirements

(vii) Education and support of hospital and health service personnel in the effective selection and use of products

(viii) Management of any existing hospital-owned stock

(ix) Where required by the health service, removal of any existing dispensers or brackets

(x) Repair of any consequent damage to surfaces and any associated costs.

(xi) Use of any successful Respondent third party suppliers or subcontractors (including their relevant licences, such as electrical or plumbing licences)

(xii) Ability to comply with specific health service requirements for:

- Contractor induction process (e.g., iPro LIVE)
- Engineering requirements in accordance with the National Construction Code
- Contractors are required to have a valid Police Check and may require a Working with Children Check
- Notwithstanding clause 25, the process for establishing Service Level Agreements with participating hospitals and health services.

Appendix 2 - Compliance Requirements

A2. Standards

Australian Standards, Orders, Legislation and Regulations

i. It is the responsibility of the Respondent to ensure that all products offered comply with the Compliance Requirements listed below. This is not an exhaustive list, Respondents must ensure they comply with any other Compliance Requirements that are not listed below, this includes primary and subordinate instruments of the State and Commonwealth, and any relevant amendments, revisions, or consolidations.

ii. The relevant legislation for Hand Hygiene, Disinfectants and Chemical Products may include, but is not limited to:

STANDARD NUMBER	STANDARD NAME
Standard 3– Preventing and Controlling Healthcare Associated Infections	National Safety and Quality Health Service Standards NSQHSS by Australian Commission on Safety and Quality in Health Care (ACSQHC).
AS 5369: 2023	Reprocessing of reusable medical devices and other devices in health and non-health related facilities
Therapeutic Goods Order 104: 2019	Standard for Disinfectants and Sanitary Products
AS/NZS 4146: 2000	Laundry Practice
AS 3789.5:1994	Textiles for health care facilities and institutions - Wool blankets - Laundering procedures.
AS/NZS 3733: 2018	Textile floor coverings - cleaning maintenance of residential and commercial carpeting
Australian Commission on Safety and Quality in Health Care	Antimicrobial Stewardship Clinical Care Standard: November 2020
ISO 14021: 2016	Environmental labels and declarations—Self-declared environmental claims (Type II environmental labelling)
ISO14025: 2006	Environmental labels and declarations -- Type III environmental declarations -- Principles and procedures
ISO 15883-1: 2006	Washer-disinfectors. Part 1: General requirements, terms and definitions and tests.
ISO 15883-2: 2006	Washer-disinfectors. Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
ISO 15883-3: 2006	Washer-disinfectors. Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers

STANDARD NUMBER	STANDARD NAME
ISO 15883-4:2018	Washer-disinfectors. Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes.

A2. Legislation

(i) The references to the below legislation include any amendments, revisions, or consolidations to those references.

a. Therapeutic Goods (Medical Devices) Regulations 2002.

b. Therapeutic Goods Act 1989; and

c. Therapeutic Goods Administration, Uniform Recall Procedure for Therapeutic Goods (V2.3 June 2022), Commonwealth of Australia.

d. Therapeutic Goods Administration (2023), Australian Regulatory Guidelines for Medical Devices.

e. ISO13485:2016 – Medical Devices Quality Management Systems. References Table of Subcategory Definitions; last review 2020

f. Dangerous Goods (Storage and Handling) Regulations 2022.

g. Environmental Protection Act 2017.

h. Occupational Health and Safety (Manual Handling) Regulations 2007

i. Occupational Health and Safety Act 2004: Version 043: Authorised Version incorporating amendments as at 26 October 2022.

j. Occupational Health and Safety Regulations 2017 (OHS Regulations)

A2. Guidelines and Other References

(i) The references to the below guidelines include any amendments, revisions, or consolidations to those guidelines.

a. Australian Guidelines for the Prevention and Control of Infection in Healthcare, Canberra: National Health and Medical Research Council (2019)

b. The Australia New Zealand Food Standards Code - Standard 3.2.2 - Food Safety Practices and General Requirements. July 2023

c. Australian Commission on Safety and Quality in Health Care – National Hand Hygiene Initiative Implementation Guide, July 2023

d. Australian Commission on Safety and Quality in Healthcare

e. Australian Competition and Consumer Commission guidance on Green Marketing and the Australian Consumer Law for general advice 2011

f. The Code of Practice for the Storage and Handling of Dangerous Goods 2022

g. Model Code of Practice - Labelling of Workplace Hazardous Chemicals 2020

h. Acorn Standards 16th Edition

Drapes & Clinical Protective Apparel

Tenderers must provide the following information in the product description of the Tender Response Worksheet, including:

a. Generic Information of the Product
   (i) Brand Name
   (ii) Type
   (iii) Material
   (iv) Size
   (v) Shape
   (vi) Dimensions
   (vii) Colour
   (viii) Sterile or non-sterile
   (ix) Single use or re-usable
   (x) Biodegradability
   (xi) Compliance to Standards, Orders, Legislations and Regulations as outlined in Appendix 2

b. Product Information that is applicable to the protective apparel categories
   (i) Fluid resistance for e.g., Impervious/ non impervious or AAMI level
   (ii) Bacterial Filtration Efficiency (BFE)
   (iii) Hypoallergenic application
   (iv) Antifog application
   (v) Where PPE are claimed to be recommended for use during the preparation and administration of cytotoxic drugs, Tenderers shall advise:
      - Treatments or processes that the PPE has undergone during the manufacturing process to support this claim.
      - Independent testing data to support these claims.
      - This information shall also be made available to hospitals/health services upon request.
      - When worn in accordance with manufacturer's instructions, PPE recommended for use during the preparation and administration of cytotoxic drugs shall provide protection against commonly used cytotoxic agents.
      - Gowns recommended for use during preparation and administration of cytotoxic drugs shall be of sufficient length with knitted cuffs of gowns or coveralls worn by the operator.

c. Additional Specifications to the individual category

1 Category 15 – Respiratory Protective Face Masks

1.1 Masks with ties shall be packaged in a manner that facilitates easy individual separation upon removal from packaging and dispensing boxes.

1.2 All masks offered shall have a minimum nominal tie length of greater than 300 millimetres.

1.3 Masks for laser plume protection shall provide filtration of particles to 0.1 micron.

2 Category 16: Respirators

2.1 Respirators shall have an IFU for fit testers.

2.2 Masks must have headbands and shall be packaged in a manner that facilitates easy individual separation upon removal from packaging and dispensing boxes.

2.3 At minimum, respirators must have level 1 Fluid Resistance

3 Category 17: Eye and Face protective Device

3.1 A range of both single use and reusable personal eye and face protective devices are required to protect health care workers and patients from the risk of splashing, splattering, or spraying of blood or body substances.
3.2 Be shaped and sized to fit most users and head shaped.
3.3 Non-metallic
3.4 Made of lightweight material
3.5 Optically clear, non-tinted, non-reflective and distortion free
3.6 Preference will be given to eye and face protective devices that incorporate scratch-resistant lenses and visors and are anti-fog.
3.7 be non-irritant when subjected to perspiration.
3.8 not discolour the skin
3.9 be designed to minimise any risk of skin irritation or abrasion.
3.10 Cleaning instructions shall also be provided where any portion of the face or eye shields is indicated to be reusable.
3.11 Replacement visors and lenses shall be packaged in a manner that protects them from damage and contamination during normal storage, fitting and handling.

4 Category 18: Clinical Overshoes Cover

4.1 Shoe covers shall be sufficiently robust and durable to maintain structure during recommended use.
4.2 Elastic shall be securely bonded around the opening edge of the overshoe in a manner that permits full stretch of the opening.
4.3 Fluid resistant
4.4 The non-skid layer on the shoe covers shall not peel off or mark floor surfaces during recommended use.
4.5 Dimensions of the of the polypropylene shoe covers shall have a minimum nominal stretched:

- length of 390mm
- opening of 230mm

5 Category 19: Headwear

5.1 Headwear shall be designed, constructed and of a range of sizes and colours to provide full coverage for most people.
5.2 Headwear shall be made of non-woven polypropylene or similar fabric that is:
5.2.1 Breathable
5.2.2 of sufficient tensile strength to avoid being torn during normal donning and wear.
5.3 Elastic shall be securely bonded around the circumference of the bouffant and beret caps in a manner that permits full stretch of the opening.
5.4 Bouffant and beret style caps shall have a minimum nominal stretched diameter of 500mm.
5.5 Surgeon caps shall have a minimum nominal lower border length (circumference of cap plus ties) of 1000mm.
5.6 Balaclavas shall have a minimum nominal lower border length (circumference of balaclava plus ties) of 1200mm.
5.7 Scarves shall be triangular and have a minimum nominal diagonal length of 1350 mm.

6 Category 20: Patient Underwear

6.1 Underwear should be breathable.
6.2 of sufficient tensile strength to avoid being torn during normal donning and wear.
6.3 Incorporate an elastic waistband.

6.4 Elastic shall be securely bonded around the circumference of the waist and leg openings in a manner that permits full stretch of the opening.
6.5 Opaque or of solid colour

7 Category 21: Non-Sterile Single Use Gowns for Patient Use

7.1 All single use patient gowns offered shall be opaque to maintain patient dignity.

8 Category 22: Single Use Isolation Gowns

8.1 with a high cut neckline.
8.2 air and moisture vapour permeable
8.3 low noise.
8.4 incorporate elastic sleeve ends or knitted cuffs/ thumb loops.
8.5 Where knitted cuffs are incorporated, they shall be securely bonded (e.g. heat, ultrasonic bonded) to the sleeves of the gown.
8.6 Seams must be bonded (e.g. heat, ultrasonic bonded) for cytotoxic gowns.
8.7 Sterile, single use gowns for clinical use shall be:
8.7.1 individually wrapped with the expiry date printed clearly on the outer packaging.
8.7.2 packaged in a manner that facilitates removal from the outer wrap without compromising the sterility of the inner wrap and contents.

9 Category 23: Single Use Surgical Gowns

9.1 be air and moisture vapour permeable.
9.2 be long sleeved with knitted cuffs that are securely heat bonded to the sleeves of the gown.
9.3 be wrap around style, incorporating a tie carrier to facilitate tying of the external tie.
9.4 be folded in a manner that facilitates donning without compromising the sterility of the product.
9.5 incorporate a high cut neckline.
9.6 Single use surgical gowns shall be:
9.6.1 individually wrapped with the expiry date printed clearly on the outer packaging.
9.6.2 packaged in a manner that facilitates removal from the outer wrap without compromising the sterility of the inner wrap and contents.
9.7 The contents shall be wrapped in the inner wrap in a manner that allows:
9.7.1 the inner wrap to be opened and draped to form a sterile field for the contents.
9.7.2 opening to expose and remove the sterile contents without compromising the sterility of the enclosed gown.
9.8 Each single gown shall be packaged with a minimum of:
9.8.1 one woven towel or
9.8.2 two non-woven towels.
9.9 Woven towels shall be:
9.9.1 low linting
9.9.2 of various sizes but not less than 35cm X 55cm to allow for effective hand drying and non-white.
9.10 Non-woven towels shall be:
9.10.1 made of suitably absorbent material that will not tear or break up when in normal use.
9.10.2 low linting
9.10.3 of sufficient size to allow for effective hand drying.

10 Category 24 – Disposable Scrubs

10.1 Disposable scrubs can include tops, pants, sets, maternity sizing and warming jackets across a variety of sizes and colours. Disposable scrubs shall be packaged with an expiry date on the outer packaging.
10.2 Disposable scrubs shall be made from low linting material, be anti-static and fluid resistant.

11 Category 25 – Disposable Aprons

11.1 Apron ties shall be a minimum length of 450mm.
11.2 Disposable aprons shall be individually packaged with the expiry date on the outer packaging.
11.3 aprons shall be packed in a manner that facilitates the easy selection of a single apron.

12 **Category 26- Disposable Anti-microbial Curtains and Screens**

12.1 Curtains must be folded and packaged in a sequence that facilitates their positioning without compromising the fold of the curtain.
12.2 Installation and Service – respondents must provide installation services free of charge if tracks, wheels, curtains, and other related components are purchased from a single supplier.
12.3 Fire retardant as standard.

Supplementary: All Drapes

a. Product Specific Information that is generic to the drapes categories:

(i) General purpose drapes shall:

a. have a crease that will not affect fluid management or the drapability of the drape.
b. be folded and packaged in a sequence that facilitates their positioning without compromising the sterility of the drapes.
c. have seams constructed to prevent fluid strikethrough.
d. have, where adhesive tape is incorporated for positioning purposes, opaque or coloured backing paper that distinguishes it from the operating field.
e. have an absorbent area to assist in fluid management.
f. be designed for trolleys, tables, bowl stands providing adequate cover to maintain sterility.
g. be resistant to tears, punctures, and abrasions.
h. be comfortable and incorporates a soft layer for the patient.
i. be tapered to suit application to limbs.
j. be manufactured from low linting material.
k. be fire retardant.
l. indicate the sequence for opening the drape.

(ii) Specialty drapes shall:

a. include tracking stickers for all items.
b. be double wrapped.

c. indicate the sequence for opening the drape (preference will be given).

d. incorporate labels to assist with correct application (equipment drapes).

e. include drape features where applicable for e.g., instrument pouches etc.

f. be free from glare.

13 Category 27 – Adhesive Incise Drapes

13.1 A range of single use, sterile adhesive incise drapes is required to meet clinical needs.

13.2 All antimicrobial impregnated drapes shall have the expiry date printed on the outer packaging.

13.3 All adhesives incise drapes shall have backing film that is removed evenly and cleanly to expose the adhesive surface.

13.4 Incise drapes must have a description of the position of the adhesive window on the outer packaging.

14 Category 28 – Drapes

14.1 General drapes must indicate the sequence for opening the drape.

14.2 A range of sizes of sterile impervious stockinette is required to meet clinical needs. Stockinette shall consist of a soft inner layer and an impervious outer layer.

14.3 Instructions for application shall be included on the unit packaging and box.

14.4 A range of sterile, single use, single or double wrapped, specialty drapes is required to meet clinical needs.

15 Category 29 –Drape Accessories

15.1 Directions for use shall be included on the unit packaging.

15.2 Accessories may be sterile or non-sterile.

15.3 Pouches must be non-impervious and have suction ports

16 Category 30 – Equipment Covers

16.1 Equipment covers shall be packaged in a manner that allows opening to expose and remove the sterile contents without compromising the sterility of the cover.

16.2 Where equipment covers are designed for a brand-specific piece of equipment, Respondents shall include the compatible equipment brand. This includes but is not limited to use across the full range of surgical specialities including laparoscopic surgery, microscopes, fluoroscopy units, ultrasound probes.

16.3 Lens and eye piece covers incorporated in camera and microscope drapes shall not adversely affect visual quality. The lens cover shall be removable from the drape where applicable.

16.4 Where adhesive tape is incorporated for positioning purposes, the backing paper shall be opaque or coloured to distinguish it from the operating field.

Appendix 3 – Compliance Requirements

A2. Standards

Australian Standards, Orders, Legislation and Regulations

i. It is the responsibility of the Respondent to ensure that all products offered comply with the Compliance Requirements listed below. This is not an exhaustive list; Respondents must ensure that they comply with any other Compliance Requirements that are not listed below. This includes primary and subordinate instruments of the State and Commonwealth and any relevant amendments, revisions, or consolidations.

ii. The relevant legislation for HPVITS2024-194 may include, but is not limited to:

STANDARD NUMBER	STANDARD Title
AS 5369:2023	AS 5369:2023 Reprocessing of reusable medical devices and other devices in health and non-health related facilities
AS 4381:2015	Single-use face masks for use in health care.
ASTM F2100-23	Standard Specification for Performance of Materials Used in Medical Face Masks
ASTM F2101-23	Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
F1862M-17	Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
ASTMF1671	Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as A Test System
ASTM F1670	Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood
AAMI PB70:2012	Liquid Barrier Performance and Classification of Protective Apparel and Drapes in Health Care Facilities
NFPA 702-1980	NFPA 702: Standard for Classification of the Flammability of Wearing Apparel
AS/NZS ISO 16972:2023	Respiratory protective devices — Vocabulary and graphical symbols
EN149 +A1	Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking
42 CFR 84	NIOSH Guide to the Selection and Use of Particulate Respirators

A2. Legislation

(i) The references to the legislation below include any amendments, revisions, or consolidations to those references.

a. Therapeutic Goods (Medical Devices) Regulations 2002

b. Therapeutic Goods Act 1989

c. Occupational Health and Safety Regulations 2017

d. Occupational Health and Safety (Manual Handling) Regulations 1999

A2. Guidelines and Other References

(ii) The references to the guidelines below include any amendments, revisions, or consolidations to those guidelines.

a. Australian Guidelines for the Prevention and Control of Infection in Healthcare, Canberra: National Health and Medical Research Council (2019)

b. Uniform Recall Procedure for Therapeutic Goods (URPTG) (V2.3, June 2022). Therapeutic Goods Administration (2011), Australian Regulatory Guidelines for Medical Devices.

c. Acorn Standards 16th Edition

d. System or procedure packs, Guidance for sponsors, manufacturers, and charities – Version 1.1 Jan (2024), Therapeutic Goods Administration

Appendix 4 – Product List

a. Preference will be given to Respondent offering the best value for money across and/or with product categories called for in this Statement of Requirements. Exceptions to this will be for niche product ranges only.

Category		Subcategory	
1	Examination Gloves	01.01	Examination Gloves, Non-Latex, Non-Sterile, Standard Cuff
		01.02	Examination Gloves, Non-Latex, Non-Sterile, Long Cuff
		01.03	Examination Gloves, Non-Latex, Non-Sterile, Extra-Long Cuff
		01.04	Examination Gloves, Non-Latex, Sterile, Standard Cuff
		01.05	Examination Gloves, Non-Latex, Sterile, Long Cuff
		01.06	Examination Gloves, Non-Latex, Sterile, Extra-Long Cuff
2	Surgical Gloves	02.01	Surgical Gloves, Overgloves, Latex
		02.02	Surgical Gloves, Overgloves, Non-Latex
		02.03	Surgical Gloves, Undergloves, Latex
		02.04	Surgical Gloves, Undergloves, Non-Latex
		02.05	Surgical Gloves, Combination, Latex
		02.06	Surgical Gloves, Combination, Non-Latex
3	Glove Dispensers	3.01	Dispensers for Examination Gloves
4	Alcohol-Based Hand Rubs	04.01	Alcohol-Based Hand Rubs
		04.02	Alcohol-Based Hand Rubs with Antiseptic
		04.03	Surgical Alcohol-Based Hand Rubs
5	Non-Medicated Hand Wash Solutions	05.01	Non-Medicated Hand Wash Solutions
6	Medicated Hand Wash Solutions	06.01	Medicated Hand Wash Solutions with Povidone Iodine
		06.02	Medicated Hand Wash Solutions with Chlorhexidine
		06.03	Medicated Hand Wash Solutions with Triclosan
7	Moisturiser	07.01	Moisturisers

Category		Subcategory	
8	Surface and Cleaning Wipes	08.01	Surface Cleaning Wipes, Disinfectant
		08.02	Surface Cleaning Wipes, Neutral Detergent
		08.03	Surface Cleaning Wipes, Alcohol
9	Chemical Surface Cleaners and Disinfectants	09.01	Chemical Hard Surface Cleaners, All Purpose
		09.02	Chemical Hard Surface Cleaners, Glass
		09.03	Chemical Hard Surface Cleaners, Bathroom
		09.04	Chemical Hard Surface Cleaners, Toilet
		09.05	Chemical Hard Surface Cleaners, Stainless-Steel
		09.06	Chemical Hard Surface Cleaners, Hard Floor
		09.07	Chemical Disinfectants, Soft furnishings
		09.08	Chemical Hard Surface Cleaners, Floor Polish
		09.09	Chemical Cleaners, Carpet
10	Food Service Chemicals	10.01	Food Service Chemicals, Food Grade Sanitiser
		10.02	Food Service Chemicals, Enzymatic Kitchen Cleaning Chemical
		10.03	Food Service Chemicals, Mechanical Dishwashing Chemical
		10.04	Food Service Chemicals, Hand Dishwashing Chemical
		10.05	Food Service Chemicals, Rinse Aid
		10.06	Food Service Chemicals, Degreaser
		10.07	Food Service Chemicals, Oven Cleaner
		10.08	Food Service Chemicals, Additional Components
11	Washer Disinfector Chemicals	11.01	Utility Washer Chemicals, Utensil Detergent, Manual
		11.02	Utility Washer Chemicals, Utensil Detergent, Auto-Dispensing
		11.03	Utility Washer Chemicals, Rinse Aid, Manual
		11.04	Utility Washer Chemicals, Rinse Aid, Auto-Dispensing
		11.05	Utility Washer Chemicals, Machine Descaler, Manual

Category		Subcategory	
		11.06	Utility Washer Chemicals, Machine Descaler, Auto-Dispensing
		11.07	Utility Washer Chemicals, Water Softener, Manual
		11.08	Utility Washer Chemicals, Water Softener, Auto-Dispensing
		11.09	Utility Washer Chemicals, Additional Components
		11.10	Pan Washer Chemicals
12	Laundry Chemicals	12.01	Laundry Chemicals, Laundry Detergent
		12.02	Laundry Chemicals, Laundry Detergent, Enzyme Based
		12.03	Laundry Chemicals, Laundry Detergent, Ozone Chemical
		12.04	Laundry Chemicals, Fabric Softener
		12.05	Laundry Chemicals, Bleach
		12.06	Laundry Chemicals, Sanitiser
		12.07	Laundry Chemicals, Destainer
		12.08	Laundry Chemicals, Additional Components
13	Reusable Medical Device Wipes	13.01	Low Level Reusable Medical Device Wipes
		13.02	Intermediate Level Reusable Medical Device Wipes
		13.03	High Level Reusable Medical Device Wipes
		13.04	Detergent Reusable medical Device Wipes
14	Accessories – Dispensers, Brackets, Pumps and Chemical Dispensers including Automated Chemical Dispensing and Dosing Systems (ACDDS)	14.01	Hand Hygiene Dispensers, Plastic
		14.02	Hand Hygiene Dispensers, Metal
		14.03	Hand Hygiene Brackets, Plastic
		14.04	Hand Hygiene Brackets, Metal
		14.05	Container Pumps
		14.06	Wipes Dispensers and Brackets
		14.07	Chemical Dispensers, Manual
		14.08	Chemical Dispensers, Automated Chemical Dispensing and Dosing Systems (ACDDS)

Category		Subcategory	
15	Respiratory Protective Face Masks	15.01	Respiratory Face Masks – Level 1
		15.02	Respiratory Face Masks – Level 2 with Visor
		15.03	Respiratory Face Masks – Level 2 without Visor
		15.04	Respiratory Face Masks – Level 3 with Visor
		15.05	Respiratory Face Masks – Level 3 without Visor
		15.06	Respiratory Face Masks – Paediatric
		15.07	Respiratory Face Masks – Laser Face Masks
		15.08	Respiratory Face Masks – Dispenser and Brackets
16	Respirators	16.01	Respirators, P2/N95/ FFP2
17	Eye and Face Protective Devices	17.01	Eye and Face Protective Devices, Safety Spectacles
		17.02	Eye and Face Protective Devices, Wide Vision Goggles
		17.03	Eye and Face Protective Devices, Eye Shields
		17.04	Eye and Face Protective Devices, Face Shields
		17.05	Eye and Face Protective Devices, Replacement Parts
18	Clinical Overshoes Cover	18.01	Clinical Overshoes Cover, Polypropylene, Non-Slip Base
19	Headwear	19.01	Headwear, Bouffant/Beret
		19.02	Headwear, Cap
		19.03	Headwear, Balaclava
		19.04	Headwear, Scarf
		19.05	Cultural Coverings, Beard
		19.06	Cultural Coverings, Hijab
20	Patient Underwear	20.01	Single-Use Patient Underwear
21	Non-Sterile Single-Use Gowns for Patient Use	21.01	Patient Gowns Short Sleeve
		21.02	Patient Gowns Long Sleeve
22	Single-Use Isolation Gowns	22.01	Isolation Gowns
		22.02	Isolation Gowns, Cytotoxic

Category		Subcategory	
23	Single-Use Surgical Gowns	23.01	Surgical/Procedure Gowns, Long Sleeved Sterile, Tie Back or Wraparound, Fluid Repellent (Single Pack) (AAMI Level 2)
		23.02	Surgical/Procedure Gowns, Long Sleeved Sterile, Tie Back or Wraparound, Fluid Repellent (Double Pack) (AAMI Level 2)
		23.03	Surgical/Procedure Gowns, Long Sleeved Sterile, Tie Back or Wraparound, Impervious (Single Pack) (AAMI Level 3)
		23.04	Surgical/Procedure Gowns, Long Sleeved Sterile, Tie Back or Wraparound, Impervious (Double Pack) (AAMI Level 3)
		23.05	Surgical/Procedure Gowns, Long Sleeved Sterile, Tie Back or Wraparound, Impervious (Single Pack) (AAMI Level 4)
		23.06	Surgical/Procedure Gowns, Long Sleeved Sterile, Tie Back or Wraparound, Impervious (Double Pack) (AAMI Level 4)
24	Disposable Scrubs	24.01	Disposable Scrubs, Tops
		24.02	Disposable Scrubs, Bottoms
		24.03	Disposable Scrubs, Sets
		24.04	Disposable Scrubs, Warming Jackets
		24.05	Disposable Scrubs, Maternity
25	Disposable Aprons	25.01	Disposable Aprons
		25.02	Disposable Aprons, Dispensers
26	Disposable antimicrobial Curtains and Screens	26.01	Disposable Antimicrobial Curtains, Standard
		26.02	Disposable Antimicrobial Curtains, Disposable Mobile Screen Covers
		26.03	Disposable Antimicrobial Curtains, Mesh
		26.04	Disposable Shower Screen and Curtains
		26.05	Disposable Antimicrobial Curtains, Curtain Hooks, and Wheels
27	Adhesive Incise Drapes	27.01	Adhesive Incise Drape, General
		27.02	Adhesive Incise Drape, Antimicrobial Impregnated

Category		Subcategory	
28	Drapes	28.01	Plastic drapes
		28.02	Drape sheets without adhesive
		28.03	Drape sheet with adhesive
		28.04	Aperture Drapes
		28.05	Split Drapes/ U-Drapes
		28.06	Screen Drapes
		28.07	Back Table Covers
		28.08	Mayo covers
		28.09	Stockinette and Leggings
		28.10	Urology Drapes
		28.11	Orthopaedic Drapes
		28.12	Hand Drapes
		28.13	Gynaecology & Obstetrics Drapes
		28.14	Cardio Thoracic/Angiopathy Drapes
		28.15	Vascular Drapes
		28.16	General Surgical Drapes
		28.17	Laparoscopic General Surgical Drapes
		28.18	Paediatric Drapes
		28.19	Neurology Drapes
		28.20	ENT Drapes
		28.21	Ophthalmic Drapes
		28.22	Specialised Drapes
29	Drapes Accessories	29.01	Drapes Accessories
30	Equipment Covers	30.01	Equipment Covers, Equipment
		30.02	Equipment Covers, Microscope Cover
		30.03	Equipment Covers, Fluoroscopy Unit Cover
		30.04	Equipment Covers, Probe Cover