HealthShare Victoria

Invitation to Supply

ITS Number:	HPVITS2023-009
ITS Name:	Continence Management Products
Closing Date and Time:	22 March 2023, 14:00 AEDT

PART 4: STATEMENT OF REQUIREMENTS

1. Participating Health Services

a. The Participating Health Services for this ITS 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 organization as follows:

a. N/A

2. Scope

a. The scope of this ITS includes:

(i) Continence Management Products used in most clinical settings, including:

- all critical care areas, from neonate to adult
- general wards, aged care, and departments

(ii) Products that are compatible with a range of equipment systems, including:

- Faecal Management Systems

3. Product Categories

a. A complete range of Continence Management Products is required for treatment of patients across Victorian Public Health Services

b. The 24 categories required include:

Category Number	Category Description
01	URINE DRAINAGE BAGS, BEDSIDE TYPE WITH SAMPLING PORT
02	URINE DRAINAGE BAG HOLDERS, BEDSIDE TYPE
03	URINE DRAINAGE BAGS, LEG TYPE
04	LEG TYPE URINE DRAINAGE BAGS, STRAPS AND HOLDERS
05	MALE INCONTINENCE SHEALTHS (EXTERNAL URINARY CATHETER)
06	INDWELLING URETHRAL CATHETERS
07	URETHRAL CATHETER ANCHORING DEVICES
08	CATHETER VALVES
09	INTERMITTENT / NELATION URETHRAL CATHETERS AND DILATORS
10	URODYNAMIC CONSUMABLES
11	CONTINENCE PADS & STRETCH PANTS FOR CONTINENCE PADS
12	NOT TENDERED – CONSOLIDATED IN CATEGORY 11
13	DISPOSABLE PULL ON PADS – PROTECTIVE UNDERWEAR – ADULT
14	PAEDIATRIC NAPPIES AND TRAINING PANTS
15	SKIN CARE PRODUCTS
16	FAECAL MANAGEMENT SYSTEMS AND KITS
17	RECTAL TUBES

18	UNDERLAY PROTECTORS AND UNDERPADS
19	SPIGOTS
20	BLADDER EVACUATORS
21	SUPRA-PUBIC CATHETERS AND KITS
22	BEDPANS AND URINALS
23	COMPACT CATHETERS
24	CATHETER KITS, PATIENT DISCHARGE (TAKE HOME)

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 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) **HPVC2016-009 Continence Management Products**

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 to 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.

d. Individual product packaging should include (where applicable):

   (i) whether the product is sterile;

   (ii) whether the product is MRI compatible (implantable products);

   (iii) whether the product (or packaging) contains latex or is latex-free; and
   (iv) tracking labels.

8. Infection Control

a. Where applicable, all items must meet the requirements of the Australian Guidelines for the Prevention and Control of Infection in Healthcare (2019) and for reusable items must meet the disinfection standard of AS/NZS 4187.

b. Upon request by Participating Health Services, successful Respondents must provide cleaning details for all reusable products.

9. Sustainability criteria

a. The impact on environmental sustainability, social benefit to Victorians, and ethical aspects of supply chains, goods, and services are considered as part of the overall value for money of the tender offers under Victoria's Social Procurement Framework and various other policies of the Victorian Government, HSV and the Participating Health Services.

b. Successful Respondents are expected to maintain or improve on their use of environmentally sustainable business practices throughout the lifetime of any resulting Agreement.

c. Respondents are invited to respond through the HSV Procurement Portal the requested information on their environmental management practices, and products sourced, for evaluation.

d. The Respondent should provide supporting information for product and its accompanying packaging where applicable under the following criteria:

   (i) Materials used in products and packaging, including confirmation of recycled content, if any

   (ii) Ability to be recycled through the waste management systems of Participating Health Services

   (iii) Substances of Concern

   (iv) Sustainable sourcing certifications

9b. Substances of Concern

a. Products (including their accompanying packaging) should be latex-free, unless otherwise stated.

b. Products should be free of Phthalates listed

   (i) Butyl Benzyl Phthalate

   (ii) Di(2-ethyl hexyl)phthalate (DEHP)

   (iii) Di-isodecyl Phthalate (DIDP)

   (iv) Di-n-butyl Phthalate (DBP)

(v) Di-n-hexyl Phthalate (DnHP)

(vi) Diisononyl Phthalate (DINP).

c. Products should be free of perfluoroalkyl or polyfluoroalkyl substances (PFAS).

d. If a product contains a listed Substance of Concern it must be identified to HSV and the health services

9c Sustainability Certifications

e. Representations of environmentally preferable goods, sustainable sourcing certifications etc. will be reviewed based on shortlisting or provisional award, and additional supporting documentation may be requested.

f. Respondents making environmental claims are recommended to consider the advice “Green marketing and the Australian Consumer Law” published by the Australian Competition & Consumer Commission.

g. Successful Respondents will supply all certification documents and supporting details to HSV in electronic format for inclusion in the relevant section of the HSV website to share with Participating Health Services.

h. Goods awarded based on environmental or ethical sourcing credentials cannot be replaced with a product of lesser credentials unless permitted by HSV during review of a Variation to a Good under Part 5 Deed of Standing Offer

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. 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.

(viii) length of stay in days if applicable

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

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

f. HSV may not consider unlabeled submissions.

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

h. 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

   (ii) Is incomplete as to clause c.

i. Product samples are not to be provided unless specifically requested by HSV, as per Part 2 clause 19 Samples.

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

11. Warranty

a. All products covered in this ITS are to be issued a warranty for 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.

12. Recall Process

a. All recalls must be managed in line with the *Uniform Recall Procedure for Therapeutic Goods* (URPTG) (V2.1, February 2019).

b. Within three (3) months of agreement commencement, all recalls and/or hazard alerts will be completed using GS1 Recall OR Recall Health.

   b. Class 1 recalls (as defined by the TGA's *Uniform Recall Procedure for Therapeutic Goods* (URPTG) (V2.1, February 2019)) must also meet the requirements under section Part 5 clause 6 Warranty, where applicable.

13. Price review

a. Upon request by the Contractor or HSV, a price review in anticipation of a further term under an option review, will be subject to the following:

   (i) will be initiated by HSV or the Contractor up to six months prior and agreed by the Contractor and HSV no later than one month before option review;

   (ii) response to pricing review must be submitted in the format requested by HSV and must be completed in full;

   (iii) any changes to the pricing, irrespective of whether it is an increase or reduction must be accompanied with the supporting evidence and justification; and

   (iv) no response by the Contractor will be deemed as an acceptance of the current Agreement terms and conditions for the option period term.

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

Delivery

14. 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.

15. Delivery

a. Continence Management Products will be delivered to the location(s) specified by Participating Health Services within the shortest possible timeframe; however, this should not exceed three (3) Business Days from receipt of order unless otherwise agreed with the Participating Health Service.

b. All deliveries are bound as per the Deed of Standing Offer Agreement, Part 5 clause 9 Acceptance and Rejection of Deliverables.

16. Urgent Deliveries

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

b. The Respondent should 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 unless otherwise agreed with the Participating Health Service.

Support

17. 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 operating 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 cleaning and sterilisation to nominated personnel and the Participating Health Services' CSSD and SSU (for reusable instruments)

   (v) training materials.

18. 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.

   (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

19. Conditional Acceptance

a. Products may be designated as 'Conditionally Accepted' for the following reasons:

   (i) Where products offered are not 'known and accepted' but represent value for money; or

   (ii) Where products are inactive and have not been in use for at least 12 months.

   (iii) Where minimum data information is not provided e.g., UNSPSC code.

b. Clause 3.10 of the Draft Deed of Standing Offer Agreement sets out terms relating to Conditionally Accepted Deliverables.

c. Products designated as 'Conditionally Accepted' may be subject to desktop and functional 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.

20. Key Performance Indicators

a. Refer to Part 5 Draft Deed of Standing Offer Agreement clause 5 and Schedule 1 – Supply Schedule, Item 17.

21. Service Level Agreement

a. Participating Health Services may enter into a Service Level Agreement (SLA) with the successful Respondent(s). The SLA may cover arrangements including, but not limited to:

   (i) requirements for stock management and rotation

   (ii) arrangements for ordering, invoicing and delivery

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

   (iv) communication arrangements for product recalls and safety alerts (refer to Part 4 clause 12 Recall Process).

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.

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 finalized.

Product Categories Specification

Category 1. Urine Drainage Bags, Bedside Type with and without sampling port

a. A full range of bedside-type urine drainage bags is required to meet clinical needs. This includes:

1) a range of volumes;
2) sterile and non-sterile;
3) a range of tubing lengths and diameters;
4) overnight bags;
5) with and without:

I. an integral measuring burette;
II. a drainage port;
III. a non-return valve.

c. All Bedside urine drainage bags shall incorporate:

1) reinforced holes for insertion on a hanging device; or
2) an integral hanging device.

d. All Bedside urine drainage bags shall have an integral needleless sampling port.

e. Preference is for Non return valves

f. For each product offered, Respondents shall provide the following information in the Tender Response Worksheet (TRW):

1) product pricing;
2) brand name;
3) volume of the drainage bag in millilitres;
4) volume of the integral measuring burette where present, in millilitres
5) length of the tubing in centimetres;
6) inner diameter of tubing in millimetres;
7) the graduation scale of volume measurement on the bag;
8) the type of outlet mechanism e.g., lever, slide tap, non-splash
9) sterile or non-sterile.
10) presence of:
11) a drainage port;
12) non return valves;
13) an integral hanging device;
14) reinforced holes for insertion on a hanging device.

Category 2. Urine Drainage Bag Holders, Bedside Type

a. A full range of bedside-type urine drainage bag holders is required to meet clinical needs. This includes:

    1) free standing;
    2) for suspension on bed or other furniture.
    3) Urine drainage bag holders shall be constructed so that they:
    4) are durable;
    5) can be cleaned;
    6) have no rough or sharp edges.

b. For each product offered, Respondents shall provide the following information in the Tender Response Worksheet (TRW):

    1) product prices;
    2) brand name;
    3) the brand/s of drainage bags that the holder is compatible with;
    4) the dimensions of the holder in centimetres;
    5) free standing or suspension holder.
    6) Instructions for cleaning
    7) recycle instructions and compatibility

Category 3. Urine Drainage Bags, Leg Type

a. A full range of single use leg-type urine drainage bags is required to meet clinical needs. This includes:

1) a range of:
   I. volumes;
   II. tubing lengths;
   III. shapes;
   IV. outlet mechanisms e.g., *flip tap, slide tap*
2) sterile and non-sterile;
3) Contains latex or non latex;
4) with and without:
   I. a needleless sample port;
   II. adjustable tubing;
   III. a spare connector for adjusting tubing length;
   IV. leg straps
   V. volume markings on the bag.

b. All tubing shall:

1) have an easy and secure connection to a catheter;
2) be kink resistant;
3) incorporate a non-return valve.

c. All leg type drainage bags may have a backing layer on the bag to enhance patient comfort.

d. Bags may have pockets or baffles to distribute the fluid evenly

e. For each product offered, Respondents shall provide the following information in the Tender Response Worksheet (TRW):

1) product prices;
2) brand name;
3) sterile or non-sterile;
4) Latex or non latex
5) length of tubing in centimetres;
6) volume of bag in millilitres;
7) needleless sample port, where applicable;
8) leg straps
   I. length and width in centimetres;
   II. the type of material;
   III. the quantity provided e.g. one pair per bag;
9) The type of outlet mechanism on each leg-type urine drainage bag offered *e.g. lever tap, slide tap*
10) a spare connector for adjusting where applicable.
11) the type of backing material e.g., woven fabric
12) volume markings on the bag.

Category 4. Leg Type Urine Drainage Bag - Straps and Holders

a. A full range of leg-type drainage bag's straps and holders is required to meet clinical needs. This includes:

   1) disposable and reusable;
   2) strap and legging type;
   3) a range of materials including stretch mesh and non-latex;
   4) a full range of sizes, lengths and widths – ranging from paediatric to bariatric
   5) with and without non-slip backing.

b. Respondents shall advise on the Tender Response Worksheet (TRW) if devices offered are washable.

c. Where the device is washable, washing and drying instructions shall be included in the instructions for use.

d. For each product offered, Respondents shall provide the following information in the Tender Response Worksheet (TRW):

   1) product prices;
   2) brand name;
   3) the type of material *e.g., stretch mesh*;
   4) the length and width of the device in centimetres;
   5) size;
   6) the type of outlet mechanism on each leg-type urine drainage bag offered *e.g., flip tap*;
   7) presence of non-slip backing.
   8) whether the product is disposable or reusable.
   9) instructions for use are included in the packaging.
   10) recycling instructions and compatibility

Category 5. Male Incontinence Sheaths (external urinary catheter) and Penile Clamps

a. A full range of single use, male incontinence sheath is required to meet clinical needs. This includes:

    1) for adult and paediatric use;
    2) a full range of sizes and lengths;
    3) one and two pieces;
    4) latex or non-latex;
    5) with and without:
        I. integral adhesive band;
        II. single- and double-sided adhesive strip;
    6) colour coded or plain.

b. Male incontinence sheaths shall:

    1) be kink resistant;
    2) resist tearing;
    3) has an easy and secure connection to a drainage bag;
    4) include clear instructions for use including skin preparation requirements, selection of appropriate size, application and removal, recommended wear time (in hours).

c. For each product offered, Respondents shall provide the following information in the Tender Response Worksheet (TRW):

    1) product prices;
    2) brand name;
    3) size e.g., small, where applicable;
    4) diameter in millimetres;
    5) length in centimetres;
    6) integral adhesive band:
        I. width in millimetres;
        II. strength of adhesive e.g., standard or extra
    7) width and length of separate adhesive band in millimetres, where applicable;
    8) colour code if applicable
    9) one or two pieces.
    10) the availability of sizing cards to assist in product selection and application.

d. Preference may be given where sizing cards are available

e. Penile clamps shall be adjustable in size, pressure and have a range of sizes

Category 6. Indwelling Urethral Catheters

a. A full range of sterile indwelling urethral catheters is required to meet clinical needs. This includes:

    1) a range of materials including:
        I. latex;
        II. non-latex.
    2) a range of coatings, for example:
        I. silicone elastomer;
        II. hydrogel.
    3) male and female length;
    4) a range of balloon volumes;
    5) two way and three ways;
    6) a full range of gauges and lengths;
    7) a range of tips e.g., Olive tip, Coudé, Dufour
    8) a range of size (in millimeters) for drainage eyelet

b. A range of specialised urethral indwelling catheters e.g.; tipless, open ended, haematuric, and coude.

c. For each device offered, Respondents shall provide the following information in the Tender Response Worksheet (TRW):

    1) Product prices;
    2) brand name;
    3) non-latex or latex;
    4) type of coating e.g., silver, hydrogel, silicone elastomer.
    5) male or female;
    6) gauge in French gauge *e.g., 10Fr*;
    7) length of catheter in centimetres;
    8) volume of balloon in millilitres;
    9) type of tip e.g., olive tip; Coude, Dufour
    10) two or three ways.
    11) Whether catheters incorporate an X-ray detectable marker;
    12) are labelled for supra pubic use.
    13) Length of stay (in days), based on the manufacturer's recommendations

Category 7. Urethral Catheter Anchoring Devices

a. A full range of anchoring devices is required for the securing of urinary catheters to enable stabilisation to the patient's body. This includes:

    1) a full range of sizes including paediatric to bariatric;
    2) disposable and reusable.

b. Variations include:

    1) strap and adhesive types;
    2) a range of:
        I. widths and lengths;
        II. materials e.g., foam, non-latex woven elastic.

c. For each device offered, Respondents shall provide the following information in the Tender Response Worksheet (TRW):

    1) product prices;
    2) brand name;
    3) strap or adhesive device;
    4) width and length in centimetres;
    5) type of material *e.g., foam*;
    6) attachment material and form / mechanism of attachment (where applicable)
    7) disposable or reusable.
    8) the recommended length of time for use *(in days)*;
    9) if devices offered are washable.

d. Where the device is washable, washing and drying instructions shall be included in the instructions for use.

Category 8. Catheter Valves

a. A full range of sterile, single use low profile catheter valves are required to meet clinical needs. This includes a range of outlet mechanisms *e.g., flip tap*.

b. Catheter valves shall be constructed to allow direct connection via a rigid universal connector to:

    1) an urethral or suprapubic catheter;

    2) a urine drainage bag.

c. For each product offered, Respondents shall provide the following information in the Tender Response Worksheet (TRW):

    1) product prices;

    2) brand name;

    3) the type of outlet mechanism *e.g., flip tap*.

    4) the recommended length of time for use *(in days)*.

    5) recycle instructions and compatibility

Category 9. Intermittent / Nelaton Urethral Catheters and Dilators

a. A full range of sterile, single use intermittent urethral catheters is required to meet clinical needs. This includes:

1) a full range of sizes (French gauge) and lengths (centimetres);
2) if DEHP free
3) non lubricated or self-lubricating;
4) single or double wrapped;
5) a range of:
    I. connections e.g., Luer sleeve, funnel;
    II. tips e.g., Tiemann, Coudé;
6) type of material *e.g., latex or non-latex*;
7) material compliance *e.g., soft or firm*;
8) with and without accessories to facilitate self-insertion *e.g., hand guide, mirror*;
9) with or without collection bag for measurement of residual urine volume.

b. For each product offered, Respondents shall provide the following information in the Tender Response Worksheet (TRW):

1) product prices;
2) brand name;
3) size;
4) catheter gauge in French gauge *e.g., 12Fg*;
5) catheter length in centimetres;
6) non lubricated or self-lubricating;
    I. where water is required to activate lubricant, a sterile water sachet must be included
    II. Instructions for use must be included
7) type of:
    I. catheter tip *e.g., Tiemann*;
    II. connector *e.g., funnel*;
8) type of material *e.g., latex, non-latex.*
9) accessories to facilitate self-insertion *e.g., hand guide*;
10) Instructions for use on packaging
11) consideration may be given to packaging indicating length, not male or female

Category 10 Urodynamic Consumables

a. A full range of urodynamic consumables is required to meet clinical needs. This includes:

    1) catheters and pressure catheters including small gauge sizes, single and double lumen
    2) pump tubing specific to urodynamic equipment
    3) fluid administration sets and individual lines where applicable
    4) transducers, Transducer Pressure Domes and associated consumables including cartridges
    5) other urodynamic consumables

b. For this new category, where Respondents currently provide urodynamic consumables to Participating Health Services, Respondents are to populate the Sales Data Template.

c. For each product offered, Respondents shall provide the following information in the Tender Response Worksheet (TRW):

    1) Product prices;
    2) brand name;
    3) male or female;
    4) a full range of sizes (Fr gauge) and lengths (cm);
    5) sterile or non-sterile

d. General continence management consumables applicable to urodynamics that are already located in other categories of this ITS, are to remain in those categories. This includes items such as general catheters.

e. Consumables applicable to urodynamics that are already on other HSV contracts, are to remain on those contracts. This includes items such as Iohexol (Omnipaque) contrast media and syringes.

Category 11. Continence Pads & Stretch Pants for Continence Pads

a. A full range of single-use continence pads is required to meet clinical needs. This includes:

1) all-in-one, tabbed
2) inserts type pads with no adhesive
3) shield / guard pads with adhesive
4) booster pads
5) belt type pads,
6) rectangular and anatomically shaped;
7) shaped for male, female or gender-neutral use;
8) a range of:
    I. sizes, paediatric to bariatric (measured in centimeters);
    II. absorbencies (working and total capacity volumes to be indicated).
9) with or without:
    I. adhesive tabs for securing to underpants;
    II. a wetness indicator;
    III. colour coding to indicate size on packaging.
    IV. front and / or back labelling

b. A full range of stretch pants to secure continence pads is required to meet clinical needs. This includes a full range of:

1) sizes;
2) styles e.g., boy leg;
3) materials;
4) with and without colour coding.

c. Respondents shall advise on the Tender Response Worksheet if products offered are washable.

1) Where the product is washable, washing and drying instructions shall be included in the instructions for use.

d. Continence pads shall:

1) meet the following standard AS/NZS ISO 22748:2021
2) not tear or disintegrate, nor shall the absorbent layer agglomerate when used in accordance with the manufacturer's instructions.
3) including anti leak protection.

e. For each continence pad product offered, Respondents shall provide the following information the Tender Response Worksheet (TRW):

1) product prices;
2) brand name;
3) type of pad e.g., all-in-one, penile continence pouch;
4) shape of pad *e.g., rectangular* or other size in centimetres
5) wetness indicator where present;
6) recommended hip and waist size in centimetres.
7) colour code of size where applicable;
8) front or back labelling where applicable;
9) absorbency capacity in millilitres:
    I. total; and
    II. working capacity.

f. For each stretch pants for continence pad product offered, Respondents shall provide the following information in the Tender Response Worksheet (TRW):

1) Product prices;
2) brand name;
3) size e.g., small;
4) style e.g., boy leg;
5) colour code where applicable;
6) Front or back labelling where applicable
7) Description of material:

g. Respondents are to provide innovative solutions for patients with unusual leg and waist dimensions, including solutions for younger patients and male patients

h. Preference may be given to suppliers that are able to supply a broad range of types and absorbencies of continence pads.

Category 12. Not tendered

This products in this category under the exiting contract is consolidated into category 11 for this tender and the new 2023 contract.

Category 13. Disposable Pull-on pads – Protective underwear - Adult

a. A full range of disposable pull-on style pants is required to assist incontinence management. This includes:
    1) a range of:
        I. sizes;
        II. styles;
        III. absorbencies;
    2) to accommodate females, males and gender neutral;
    3) with and without:
        I. a wetness indicator;
        II. colour coding.
        III. front or back labelling
        IV. meet the following standard AS/NZS ISO 22748:2021

b. For each product offered, Respondents shall provide the following information in the Tender Response Worksheet (TRW):
    1) product prices;
    2) brand name;
    3) gender specific or neutral e.g., male, female or unisex
    4) full range of adult sizes up to bariatric (in cm)
    5) waist measurement in centimetres;
    6) style e.g., boy leg;
    7) absorbency capacity in millilitres:
    - total; and
    - working capacity.
    8) wetness indicator where present.

Category 14. Paediatric Nappies and Training Pants

a. A full range of disposable Paediatric Nappies and pull ups is required to assist incontinence management. This includes:

    1) a range of:

        I. sizes;

        II. styles;

        III. absorbencies;

    2) to accommodate females and males;

    3) with and without:

        I. a wetness indicator;

        II. colour coding.

        III. Front or back labelling

        IV. meet the following standard AS/NZS ISO 22748:2021

b. For each product offered, Respondents shall provide the following information in the Tender Response Worksheet (TRW):

    1) product prices;

    2) brand name;

    3) gender specific or neutral e.g., male, female or unisex

    4) a full range of sizes with age range indicators if applicable (including sizes for neonates and ‘preemies‘ in grams e.g.,1000 grams or range of child weights from 750gm to 1250gm)

    5) waist measurement in centimetres;

    6) style e.g., boy;

    7) absorbency capacity in millilitres:

        I. total; and

        II. working capacity.

    8) wetness indicator where present.

Category 15. Skin Care Products

a. A full range of skin care products is required to meet clinical needs. This includes:

1) a range of sizes including single and multi-use packaging;

2) a range of presentations including:

- impregnated, foams, sprays, creams, gels, pastes, powders, solutions, wipes and gloves / mitts, and wands

3) skin cleansers

4) protective films

5) moisturisers;

6) barrier creams;

7) adhesive remover.

8) Skin wipes e.g., skin cleansing, bath wipe, IAD (incontinence associated dermatitis) wipe

b. Skin care products that have been specifically developed for the management of skin conditions related to exposure to urine and faeces.

c. For each product offered, Respondents shall provide the following information in the Tender Response Worksheet (TRW):

1) product prices;

2) brand name;

3) type of product e.g., skin cleanser, barrier film;

4) active ingredients e.g., Zinc Oxide

5) volume in millilitres; or

6) percentage of ingredient by weight e.g., 1% w/w 15 grams

7) whether dimethicone is present

8) for wipes:

I. the dimensions of the wipe in millimeters;

II. the number of wipes in each container e.g., 100;

III. Whether wipes are compatible with macerater.

d. For sprays, the number of applications in each bottle;

I. Frequency of application;

II. Where an applicator is present;

III. the type of material the applicator is made of e.g., foam;

IV. the length and width in millimeters.

e. For Barrier Creams where an applicator is present:

I. the type of material the applicator is made of e.g., foam;

II. the length and width in millimetres;

III. volume of skin care product contained in the applicator in millilitres.

f. Volume in millilitres;

g. PH

h. Instructions for use of products

i. To include time of expiry after opening product

j. Material Safety Data Sheets for all products shall be available to health services in either electronic or print form, upon request.

Category 16. Faecal Management Systems and Kits

a. A full range of faecal management systems / kits is required to contain, drain and collect faecal matter to meet the clinical needs of patients. This may include:
    1) a system / kit that includes the following:
        I. a retention balloon, inflation port and flushing port;
        II. collection bag/s with scale of volume in millilitres;
        III. transparent surface to inspect faecal content;
        IV. a syringe for inflation of retention balloon;
    2) accessories e.g., collection bag.

b. Faecal collection bag shall:
    1) effectively divert and contain faecal matter;
    2) maintain a closed system; include clear instructions on how to apply the collection device.

c. For each product offered, Respondents shall provide the following information in the Tender Response Worksheet (TRW):
    1) Product prices;
    2) brand name;
    3) components of the system;
    4) as well composition i.e., contains latex?

d. retention balloon:
    1) internal diameter in millimetres;
    2) external diameter in millimetres;
    3) Volume in millilitres e.g., 45ml

e. collection bag:
    1) volume in millilitres;
    2) scale of volume measurements on collection bag;

f. volume of syringe in millilitres;

g. presence of:
    1) inflation tube;
    2) irrigation channel;
    3) flush channel.

h. Instructions for use to be included and state:
    1) length of time for use in days

i. Consideration will be given to any pressure injury risk reduction such as overinflating pop-up button with the Flexiseal protect to prevent necrosis/pressure injury to the mucosa/bowel lining

Category 17. Rectal Tubes

a. A full range of sizes of sterile, single use rectal tubes is required to meet clinical needs. This includes:
    1) coloured or clear;
    2) colour coded connectors where applicable.

b. The terminal orifice and any drainage eyes of the rectal tubes shall be smooth and free from sharp edges.

c. Rectal tubes shall be packaged individually in peel apart packaging.

d. For each product offered, Respondents shall provide the following information in the Tender Response Worksheet (TRW):
    1) product prices;
    2) brand name;
    3) gauge in French gauge *e.g.,18Fr*;
    4) tube length in millimetres;
    5) Material of manufacture e.g., PVC, silicone
    6) colour of:
        - rectal tube;
        - connector, where applicable.

Category 18. Underlay Protectors and Underpads

a. A full range of single use underlay protectors and underpads are required to meet clinical needs. This includes a range of:

    1) sizes;

    2) ply;

    3) absorbencies.

b. Single use underlay protectors and underpads shall comprise a waterproof backing film, absorbent layer and a non-woven cover stock.

c. The backing film shall envelop the absorbent layer and cover stock and be bonded to the cover stock to prevent separation of absorbent layers.

d. The Underlayer Protectors and Underpads shall not tear or layer separating, nor shall the absorbent layer disintegrate or agglomerate when wet under normal use.

e. The cover stock shall:

    1) be highly permeable to fluids;

    2) be of soft, non-abrasive texture;

    3) not disintegrate during use;

    4) wick away fluid from skin.

f. For each product offered, Respondents shall provide the following information in the Tender Response Worksheet (TRW):

    1) product prices;
    2) brand name;
    3) sizes
        I. width and length in millimetres;
        II. Sizes for use in maternity and theatre e.g.,1800x600mm(4L) OR 2250X1030mm (12L)
    4) type of material e.g., pulp filled, “moisture lock", super absorbent polymer (SAP)
    5) the ply, where applicable, *e.g., 5 ply*;
    6) Whether underpads have wings or not, i.e., to tuck under mattress
    7) total absorbency capacity in millilitres. Absorbency of at least 200ml and above
    8) method of disposal

Category 19. Spigots

a. A full range of single use spigots is required to meet clinical needs. This includes:

1) a range of sizes;
2) sterile;
3) individually packaged.

b. For each product offered, Respondents shall provide the following information in the Tender Response Worksheet (TRW):

1) product prices;
2) brand name;
3) sterile;
4) material;
5) size in millimeters;
6) colour;
7) whether the product is recyclable or not;
8) whether product is biodegradable or not.

Category 20. Bladder evacuators

a. full range of single use bladder evacuators is required to meet clinical needs. This includes:

1) sterile;
2) a range of materials including rubber, plastic;
3) a range of sizes, lengths and widths

b. For each product offered, Respondents shall provide the following information in the Tender Response Worksheet (TRW):

1) product prices;
2) brand name;
3) the type of material *e.g., latex or non-latex, plastic*;
4) the length and width of the product in centimetres;
5) filter;
    I. One way
6) size;
7) volume;
8) Instructions for use are included in the packaging.

Category 21. Supra-pubic catheters and kits

a. A range of sterile Supra-pubic catheters and kits is required to meet clinical needs. This includes:

1) material e.g., latex or non-latex
2) a range of coatings
3) balloon volume;
4) two way;
5) gauges and lengths.

b. For each product offered, Respondents shall provide the following information in the Tender Response Worksheet (TRW):

1) product prices;
2) brand name;
3) non-latex or latex;
4) type of coating e.g., silver, hydrogel, silicone elastomer.
5) gauge in French gauge *e.g., 10Fg*;
6) length of catheter in centimetres;
7) volume of balloon in millilitres;
8) Whether catheters incorporate an X-ray detectable marker;
9) are labelled for supra pubic use.
10) length of use in days based on the manufacturer's recommendations

c. For each kit tendered they should meet the specifications outlined in category 21

- For kits please provide an itemised list of contents
- Type of kit e.g.,10 French kit

Category 22. Bedpans and Urinals

a. A full range of bedpans and urinals required to meet clinical needs. This includes:

1) a full range of:
   I. pans and urinals; including spill proof;
   II. male and female;
   III. volume measurements in millilitres;
   IV. graduated urine measuring insert for toilet bowl;
   V. disposable and reusable versions;
   VI. preference for disposable versions may be given for those that are manufactured from sustainably sourced renewable resources (e.g., paperboard made from wood pulp, recycled paper, or sugarcane bagasse), noting that Substances of Concern should be avoided in any fluid resistant coatings used in the manufacture;
   VII. disposable pan and urinal cover

b..For each product offered, Respondents shall provide the following information in the Tender Response Worksheet (TRW):

1) product prices;
2) brand name;
3) shape e.g., slipper shell pan, if applicable
4) description of material; e.g., paperboard, recycled paperboard, plastic, sugarcane bagasse
   I. material type
   II. recycled content % (if applicable)
   III. sustainable forestry management certification (if applicable, e.g., for wood pulp)
   IV. confirmation of whether coating is free of PFAS or contains PFAS
5) whether product is compatible with macerater and wastewater management systems

Category 23. Compact Catheters

b. A range of sterile urethral compact catheters is required to meet clinical needs. This includes:
    1) a range of materials including:
        I. latex;
        II. non-latex.
    2) a range of coatings including:
        I. silicone elastomer;
        II. hydrogel;
    3) a range of gauges and lengths;
    4) a range of size (in mm) for drainage eyelet.

c. For each product offered, Respondents shall provide the following information in the Tender Response Worksheet (TRW):
    1) product prices;
    2) brand name;
    3) non-latex or latex;
    4) type of coating e.g., silver, hydrogel, silicone elastomer;
    5) gauge in French gauge *e.g., 10Fr*.
    6) length of catheter in centimetres;
    7) whether a bag is already attached with volumes indicated;
    8) whether product is pre-lubricated
        I. type of lubricant

Category 24 Catheter Kits, Patient Discharge (take home)

a. A full range of Patient Discharge catheters is required to meet clinical needs. This includes:
    1) A kit that includes the following:
    2) Short term packs (7-10days with review by Continence nurse of clinics:
        I. Night collection bags 2x2 litres with outlet
        II. Leg collection bags 500ml or 750 ml x 2 with outlet
        III. Catheter straps- spare pair
        IV. A booklet on catheter and drainage bag management (to be added by individual hospital)
        V. A booklet on catheter care (to be added by individual hospital or manufacturer)
        VI. A spare IDC equivalent or one size smaller than discharge catheter (long term catheter to be added by hospital)

b. Long term packs (follow up with Continence nurses/ Urology out-patient clinics within two month of discharge)
    1) Night collection bags 4x2 litres with outlet
    2) Sterile or non-sterile
    3) Leg collection bags 500ml or 750 ml x 4 with outlet
    4) Alcohol wipes x4
    5) Catheter straps
    6) Catheter procedure pack x1 60cm
    7) Syringes, 2 x10ml
    8) Water for injection, 2x10mls
    9) Cath gel syringe (lignocaine gel) x1
    10) A booklet on catheter and drainage bag management (to be added by individual hospital)
    11) A booklet on catheter care (to be added by individual hospital or manufacturer)
    12) A spare IDC equivalent or one size smaller than discharge catheter (long term catheter to be added by Hospital
    13) Catheter valve x2 sterile?

c. For each product offered, Respondents shall provide the following information in the Tender Response Worksheet (TRW):
    1) product prices;
    2) Brand name
    3) Components included in pack and quantity each
    4) length of stay for bags/catheters

d. Collection bags
    1) Volume in millilitres
    2) Scale of volume measurements on collection bag
    3) Sterile or non-sterile
    4) Type of material e.g., contains latex or non-latex

e. Volume of syringes in millilitres

Appendix 1 - Product List

Category Number	Category Description	Sub-Category Number	Sub-Category Description
01	Urine Drainage Bags, Bedside Type, with sampling port	01.01	Urine Drainage Bags, Bedside Type, No Drainage Port, Non-Sterile
		01.02	Urine Drainage Bags, Bedside Type, With Drainage Port, Non-Sterile
		01.03	Urine Drainage Bags, Bedside Type, With Drainage Port, Non-Return Valve, Sterile
		01.05	Urine Drainage Bags, Bedside Type, With Drainage Bag, Non-Return Valve, Measuring Burette, Sterile
02	Urine Drainage Bag Holders, Bedside Type	02.01	Urine Drainage Bag Holders, Bedside Type, For Suspension
		02.02	Urine Drainage Bag Holders, Bedside Type, Floor Standing
03	Urine Drainage Bags, Leg Type	03.04	Urine Drainage Bag, Leg Type, Sterile, With Needleless Sampling Port
		03.05	Urine Drainage Bag, Leg Type, Non-Sterile, With Backing Layer
		03.06	Urine Drainage Bag, Leg Type, Sterile, With Backing Layer
		03.08	Urine Drainage Bag, Leg type with Leg Straps, Sterile
		03.09	Leg Straps for Urine Drainage Bags, Leg Type
04	Leg Type Urine Drainage Bag, Strap and Holders	04.04	Legging Type, Without Non-Slip Backing Layer
05	Male Incontinence Sheaths (external urinary catheter)	05.01	Male Incontinence Sheath, Latex, One Piece
		05.02	Male Incontinence Sheath, Latex, Two Piece
		05.03	Male Incontinence Sheath, Non-Latex, One Piece
		05.04	Male Incontinence Sheath, Non-Latex, Two Piece
06	Indwelling Urethral Catheters	06.01	Indwelling Urethral Catheters, Latex, 2 Way, 30ml Balloon, Male Length
		06.02	Indwelling Urethral Catheters, Latex, 2 Way, 5/10ml Balloon, Male Length
		06.03	Indwelling Urethral Catheters, Latex, 3 Way, 30ml Balloon, Male Length
		06.04	Indwelling Urethral Catheters, Non-Latex, 2 Way, 30ml Balloon, Male Length
		06.05	Indwelling Urethral Catheters, Non-Latex, 2 Way, 5/10ml Balloon, Male Length
		06.06	Indwelling Urethral Catheters, Non-Latex, 3 Way, 30ml Balloon, Male Length
		06.07	Indwelling Urethral Catheters, Non Latex, , 3 Way, > 30ml Balloon, Male Length
		06.08	Indwelling Urethral Catheters, Non Latex , 2 Way, 5/10ml Balloon, Female Length
		06.09	Indwelling Urethral Catheters, Latex, 2 Way, 5/10ml Balloon, Female Length
07	Urethral Catheter Anchoring Devices	07.01	Urethral Catheter Anchoring Devices, Adhesive Type
		07.02	Urethral Catheter Anchoring Devices, Strap Type
08	Catheter Valves	08.01	Catheter Valve, Full Range
09	Intermittent/Nelaton Urethral Catheters and Dilators	09.01	Intermittent/ Nelaton Urethral Catheters, Funnel Connector, Straight Tip, Male Length
		09.02	Intermittent/ Nelaton Urethral Catheters, Funnel Connector, Straight Tip, Female Length
		09.03	Intermittent/ Nelaton Urethral Catheters, Funnel Connector, Tiemann, Full Range Of Sizes
		09.04	Intermittent/ Nelaton Urethral Catheters, Funnel Connector, Coude, Full Range Of Sizes

		09.05	Intermittent/ Nelaton Urethral Catheters, Luer Sleeve Connector, Straight Tip
		09.06	Catheter, Intermittent/ Nelaton, Self-Lubricating
10	Urodynamic Consumables	10.01	Catheters for Urodynamics
		10.02	Pump Tubing for Urodynamics
		10.03	Fluid Administration Sets
		10.04	Transducers and Transducer Pressure Domes and consumables
		10.05	Other Urodynamic Consumables
11	Continence Pads & Stretch Pants for Continence Pads	11.01	Continence Pads, All in One
		11.02	Continence Pads, Insert Type, Non-Adhesive
		11.03	Continence Pads, Shield/ Guard, Male and Female
		11.04	Continence Pads, Booster Type
		11.05	Continence Pads, Belt Types
		11.06	Stretch pants for continence Pads, gender specific
12	Not tendered – consolidated into Category 11.		
13	Disposable Pull-on pads – Protective underwear - Adult	13.01	Disposable Continence Pants, Full Range of Sizes
14	Paediatric Nappies and Training Pants	14.01	Paediatric Nappies
		14.02	Training Pants
15	Skin Care Products	15.01	Skin Care Products, Skin Cleanser
		15.02	Skin Care Products, Barrier Cream
		15.03	Skin Care Products, Barrier Cream with Dimethicone
		15.04	Skin Care Products, Protective Film
		15.05	Skin Care Products, Adhesive Remover
16	Faecal Management Systems and Kits	16.01	Faecal Management System
		16.02	Faecal Management System Accessories
17	Rectal Tubes	17.01	Rectal Tubes, Single Use, Full Range of Sizes
18	Underlay Protectors and Underpads	18.01	Underlay Protectors, Full Range of Plys and Sizes
		18.02	Underpads, Pulp filled or super absorbent polymer, Full Range of Sizes
19	Spigots	19.01	Spigots
20	Bladder evacuators	20.01	Bladder Evacuator, Non-latex, rubber Reservoir,
		20.02	Bladder Evacuator, Plastic Bulb,
		20.03	Bladder Evacuator, Silicone Bulb
21	Supra-pubic catheters and kits	21.03	Supra-Pubic Catheter, Latex, 2 Way, 3/5ml balloon
		21.04	Supra-Pubic Catheter, Latex, 2 Way, 10ml Balloon
		21.05	Supra-Pubic Catheter, Non-Latex, 2 Way, 3/5ml balloon
		21.06	Supra-Pubic Catheter, Non- Latex, 2 Way, 10ml Balloon
		21.07	Supra-Pubic Insertion Packs
22	Bedpans and urinals	22.01	Bedpan, disposable
		22.02	Bedpan, disposable, Slipper Style
		22.03	bedpans, reusable
		22.04	Urinal, male, disposable
		22.05	Urinal, male, disposable, Spill Proof
		22.06	Urinal, male, reusable
		22.07	Urinal, female, disposable

		22.08	Urinal, female, disposable, Spill Proof
		22.09	Urinal, female, reusable
		22.10	Bedpan and bottle cover, disposable
		22.11	Graduated Urine Measuring Insert
23	Compact catheters	23.01	Compact Catheters, range of gauges and lengths, latex
		23.02	Compact Catheters, range of gauges and lengths, non-latex
24	Catheter Kits, Patient Discharge (take home)	24.01	Catheter Kits, Discharge pack, short term sterile
		24.02	Catheter Kits, Discharge pack, short term, non-sterile
		24.03	Catheter Kits, Discharge pack, long term, sterile
		24.04	Catheter Kits, Discharge pack, long term, non-sterile

Appendix 2 - Compliance Requirements

Australian Standards, Orders, Legislation and Regulations

a. 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.

   The relevant legislation for Continence Management Products may include, but is not limited to:

STANDARD NUMBER	STANDARD NUMBER
AS/NZS 4187	Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities
IAS/ NZS ISO 22748:2021	Absorbent incontinence products for urine and/or faeces

Legislation

b. The references to the below legislation include any amendments, revisions or consolidations to those references.

   (i) *Therapeutic Goods (Medical Devices) Regulations* 2002

   (ii) *Therapeutic Goods Act* 1989

Guidelines and Other References

c. The references to the below guidelines include any amendments, revisions or consolidations to those guidelines.

   (i) NHMRC (2019) Australian Guidelines for the Prevention and Control of Infection in Healthcare (2019)

   (ii) *Uniform Recall Procedure for Therapeutic Goods* (URPTG) (V2.1, February 2019). Therapeutic