Part 4 Statement of Requirements

SCOPE

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 organisations as follows:

- Robinvale District Health Services
- Sunraysia Community Health Services Ltd
- Geteway Health

b. For a full list, refer to Schedule 4 Reporting Guidelines.

2 Product Categories

a. A complete range of Sutures, Skin Staples & Removers, and Tissue Adhesives is required for treatment of patients across Victorian Public Health Services.

b. The categories required include:

(i) Category 1 – Sutures

(ii) Category 2 – Skin Staples & Removers

(iii) Category 3 – Tissue Adhesives

c. Refer Appendix 1 for full product list.

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

e. HPV reserves the right not to consider any additional products offered.

3 Restricted and extended basket of goods

a. In the Response Worksheet Respondents may offer pricing options for both an extended basket of goods and a restricted basket of goods for each line item.

b. A restricted basket of goods would be a reduced variance of items offered in each subcategory.

c. An extended basket of goods would consist of all items listed in each subcategory listed in the Response Worksheet.

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

(i) Sutures

(ii) Skin Staples & Removers

(iii) Tissue Adhesives

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.

PRODUCT REQUIREMENTS

5 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. public ARTG certificates) in its response.

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

6 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. It is desirable for individual product packaging to 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.

7 Infection Control

a. Where applicable, all items must meet the requirements of the Australian Guidelines for the Prevention and Control of Infection in Healthcare (2010).

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

8 Substances of Concern

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

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

9 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. OR Research papers should not be provided unless specifically requested by HPV.

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.

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

e. Electronic copies should include the HPV category and subcategory numbers in the filename or identifying metadata.

f. HPV may not consider unlabelled submissions.

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

(ii) HPV reserves the right to exclude products from evaluation when the product is unidentifiable and provided information is:

- Not labelled as per Part 4 .9 .d above; or
- Is incomplete as to Part 4 .9 .c

(iii) Product samples are **not** to be provided unless specifically requested by HPV, as per Part 2 .19, Samples.

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

10 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 Part 5 Draft Deed of Standing Offer Agreement clause 3.12 Consignment Stock and/or under any relevant Service Level Agreement.

11 Warranty

a. All products covered in this ITS are to be issued a warranty for a minimum of twenty four (24) 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 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.

c. 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 4 .12 Warranty, where applicable.

DELIVERY

13 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.

14 Delivery

a. HPVITS2020-016 Sutures, Skin Staples and Tissue Adhesives will be delivered to the location(s) specified by Participating Health Services within the shortest possible timeframe; however, this must not exceed two (2) 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 7.2 Acceptance and Rejection of goods.

15 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 must 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

16 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.

17 Customer Service and Support

a. The successful Respondent must be able to deliver 24-hour, 7-day customer service and support to Participating Health Services. OR 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 24 hours a day OR 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.

f. Health service who utilise supplier supported vendor management systems must have expired stock on shelves replaced by the supplier at the cost to the supplier.

AWARD

18 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 HPV; 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 Conditional acceptance of Part 5 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.

19 Key Performance Indicators

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

20 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) the provision of products on consignment

(ii) requirements for stock management and rotation

(iii) arrangements for ordering, invoicing and delivery

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

(v) communication arrangements for product recalls and safety alerts (refer to 13 Recall / Recall Health).

b. The SLA will be in addition to the Agreement between the successful Respondent(s) and HPV, and will not alter any terms of the Agreement.

c. HPV 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 HPV within 1 week of being finalised.

Category 1 - Sutures

a. A range of sterile, single use sutures is required to meet clinical needs across all surgical specialties and areas of care, including as per ISO 10334:1994:

(i) a full range of suture materials including:

- absorbable, braided, dyed;
- absorbable, braided, undyed;
- absorbable, monofilament, dyed;
- absorbable, monofilament, undyed;
- non-absorbable, braided, dyed;
- non-absorbable, braided, undyed;
- non-absorbable, monofilament, dyed;
- non-absorbable, monofilament, undyed;
- antimicrobial, absorbable, braided, dyed;
- antimicrobial, absorbable, braided, undyed;
- antimicrobial, absorbable, monofilament, dyed;
- antimicrobial, absorbable, monofilament, undyed;
- antimicrobial, non-absorbable, monofilament, undyed;

(ii) a full range of needle gauges, shapes and configurations

(iii) with and without:

- attached needles;

Packaging

b. Products must be packaged in a manner that:

(i) maintains sterility of the contents;

(ii) retains the structural integrity of the enclosed suture;

(iii) protects the suture needle (where present);

(iv) minimises the risk of tangling the enclosed suture;

(v) on opening, presents the suture needle in a manner that facilitates loading onto a suture holder or similar application device.

c. For each suture offered, tenders must advise the following information in the Product Description on the Tender Response Worksheet:

(i) brand name of suture;

(ii) generic name of suture material;

(iii) gauge of suture;

(iv) length of suture material in centimetres;

(v) needle type;

(vi) needle shape;

(vii) needle length in millimetres;

(viii) where present, antimicrobial coating;

(ix) where more than one needle is present per thread, the number of needles;

(x) where more than one suture is present in a single foil, the number of sutures per foil.

(xi) Description of the colour of the suture

Shelf Life

d. Sutures shall have a minimum of twenty four (24) months shelf life on delivery to a hospital or health service.

e. Where remaining product shelf life is six months or less, successful tenderers must advise the receiving hospital or health service to allow for effective stock management and utilisation.

Inventory Management and Ordering

f. Tenderers must advise of the availability of an electronic suture inventory management and ordering system to support effective product use. Where present, tenderers shall provide a brief outline of the system including:

(i) establishment and ongoing use of the system;

(ii) allocation of support personnel;

(iii) process to review range and volume of stock held, including frequency of review;

(iv) management of shelf-life issues;

(v) any limitations associated with access and use;

(vi) any costs associated with its use.

g. Preference given to tenderers that provide an electronic suture inventory management and ordering system.

h. Tenderers must not pass freight and handling charges to hospitals or health services should they enter into an inventory management agreement with the tenderer.

Service Level Agreement

i. Successful tenderers must enter into a Service Level Agreement with individual hospitals or health services requiring use of an electronic suture inventory management and ordering system.

j. The agreement must cover all arrangements associated with use of the system including but not limited to those points identified in clause Category 1 - f.

Additional Information

k. The following information must be available to all contract users via hard copy or electronic means:

(i) independent research papers to support the introduction of new or modified suture materials.

Category 2 - Skin Staples & Removers

Skin Staples

a. A range of sterile, single use skin stapling devices incorporating stainless steel or equivalent skin staples is required to meet clinical needs, including:

(i) a range of staple widths and depths

(ii) a range of unit capacity

b. Tenderers must advise the following information in the product description on the Tender Response Worksheet:

(i) brand name;

(ii) staple gauge;

(iii) staple depth;

(iv) staple width;

(v) number of skin staples per stapling device

c. Tenderers must advise if skin stapling devices incorporate a viewing window to visualise the staple count.

d. Preference is for skin stapling devices that incorporate a viewing window.

e. Skin stapling devices must be packaged in peel-pack (lot number and expiry date included) to facilitate ease of access.

f. A full range of Skin Staple Removers is required to meet clinical needs.

g. Skin Staple Removers must be packaged individually in a peel pack.

h. Latex-containing products will not be considered for this tender.

Skin Staple Removers

a. A range of sterile, single use skin staple removers is required to meet clinical needs.

b. Skin Staple Removers must:

(i) be of solid construction;
(ii) have no rough or sharp edges;
(iii) cleanly and smoothly remove skin strapless;
(iv) be packaged individually in peel-pack in a manner that protects the tip from accidental damage;
(v) have the lot number and expiry date included on each peel-pack

c. For each Skin Staple Remover offered, Tenderers shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name
(ii) UNSPCS code
(iii) HPIS Classification

d. Latex-containing products will not be considered for this tender.

Category 3 - Tissue Adhesives

a. A range of sterile, single patient use cyanoacrylate tissue adhesive products (for external use) is required for the closure of skin lacerations or incisions and vascular access, including:

(i) a range of volumes

(ii) with and without an incorporated skin closure device.

b. Tissue adhesives must be:

(i) supplied in a 'ready to use' form;

(ii) easy to apply;

(iii) packaged in a manner that:

- minimises the risk of spillage, leaking or clotting of the application tip;
- protects the integrity of the contents;
- provides a barrier to microbial penetration.

c. Tenderers must advise the following information in the Product Description on the Tender Response Worksheet:

(i) brand name;

(ii) volume of adhesive in each individual unit (in millilitres).

d. Tenderers must advise the following information on the Tender Response Worksheet:

(i) setting time, in seconds;

(ii) sloughing time, in days;

(iii) requirement for refrigeration or frozen storage.

(iv) Preference given to tissue adhesives that do not require refrigeration.

Additional Information

e. The following information shall be available to all contract users via hard copy or electronic means:

(i) Material Safety Data Sheet.

Appendices to statement of requirements

Appendix 1 - Product List

Category		Subcategories	
1	Sutures	1.01	Absorbable, braided, dyed
		1.02	Absorbable, braided, undyed
		1.03	Absorbable, monofilament, dyed
		1.04	Absorbable, monofilament, undyed
		1.05	Non-absorbable, braided, dyed
		1.06	Non-absorbable, braided, undyed
		1.07	Non-absorbable, monofilament, dyed
		1.08	Non-absorbable, monofilament, undyed
		1.09	Antimicrobial, absorbable, braided, dyed
		1.10	Antimicrobial, absorbable, braided, undyed
		1.11	Antimicrobial, absorbable, monofilament, dyed
		1.12	Antimicrobial, absorbable, monofilament, undyed
		1.13	Antimicrobial, non-absorbable, monofilament, undyed
2	Skin Staples & Removers	2.01	Non-reloadable staplers
		2.02	Skin Staple Remover, Sterile, Single Use
3	Tissue Adhesives	3.01	Tissue Adhesives without an incorporated skin closure device

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 HPVITS2020-016 Sutures, Skin Staples & Removers and Tissue Adhesives may include, but is not limited to:

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

Standard Number	Standard Name
NA	Health Services Act 1988
NA	Freedom of Information Act 1982 (Vic)
NA	Local Jobs First Act 2003
NA	Education and Training Reform Act 2006
NSHQS	National Safety and Quality Health Service Standards 2017
ISO 10334:1994	Implants for surgery — Malleable wires for use as sutures and other surgical applications

Legislation

a. 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

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

(i) NHMRC (2010), Australian Guidelines for the Prevention and Control of Infection in Healthcare, Commonwealth of Australia

(ii) Uniform Recall Procedure for Therapeutic Goods (URPTG) (V2.1, February 2019). Therapeutic Goods Administration (2011), Australian Regulatory Guidelines for Medical Devices