HEALTH PURCHASING VICTORIA

Invitation to Supply

Part 5 - Statement of Requirements

Invitation to Supply Number:	HPVITS2019-019
Invitation to Supply Name:	Examination and Surgical Gloves
Closing Date and time:	Wednesday 30 January 2019, 14:00 AEST

Authorised Contact Person

David Nguyen
Category Officer

Contact through
HPV Procurement Portal

https://www.hpv.org.au/

Published: XXX

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A Introduction

1 Purpose

a. The purpose of this Part 5 - Statement of Requirements, is to:

(i) detail the scope and range of products sought under this Invitation to Supply (ITS);

and

(ii) specify the requirements that Respondents and / or their offered products must meet.

These requirements also form part of any resulting Agreement between Health Purchasing Victoria (HPV) and any successful Respondent).

2 Scope

a. HPV is seeking responses for Examination and Surgical Gloves products for use in Participating Health Services (PHS). The envisaged term of the agreement is three (3) years plus one optional two (2) year extension period.(i.e. 3+2).

b. The scope of this ITS includes:

(i) the supply of Examination and Surgical Gloves products covered in section Part 5-D2 Category Specification

(ii) Education and training

(iii) Company representative clinical attendance

c. The scope of this ITS does not include the following:

(i) Supply of PVC gloves & radiation attenuation are not included in the scope of this tender;
(ii) Supply of products that are currently in other active HPV Contracts.

3 Product Categories

a. A full list of product categories and subcategories can be found in Appendix 1 - Product List.

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

c. Only products that specifically fit within the category specification provided will be considered.

d. Preference to offers with the greatest range and best value for money across and/or within product categories (with the exception of niche product ranges) may be given.

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

4 Product Conditions

4.1 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.

4.2 Product Duplication

a. HPV will not consider any product that is subject to a current HPV Agreement.

b. The Respondent must ensure that each product is offered in only **one** subcategory.

c. It is at the Respondent's discretion to ensure that each product is submitted in the most appropriate subcategory.

4.3 Product Information

a. The Respondent must 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 Respondent's tender.

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

d. To assist in managing this material, all product information submitted must be labelled with the relevant HPV category and subcategory number, and TGA code where applicable.

Electronic copies must include the HPV Category and subcategory numbers in the filename or identifying metadata.

HPV may not consider unlabelled submissions.

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

f. HPV reserves the right to exclude products from evaluation when the product is unidentifiable and provided information is:

(i) Not labelled as per Part 5 section D; or
(ii) Is incomplete as to Part 5 section C.

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

h. Respondents are to provide for evaluation purposes samples of submitted products and accessories. **For products currently on the HPV contract, no samples are required**. Sample provided should include:

(i) sample pack to include a range of sizes for each new product. (Eg: sizes 7 & 8, Max four pairs of each size)
(ii) sterile or non-sterile;
(iii) a list of all samples provided; and
(iv) instructions for use, where applicable.

i. All samples provided should be:

(i) new and unopened;
(ii) packed, sealed and labelled; and
(iii) include supporting specifications and relevant data.

j. Each sample submitted should be clearly labelled with the following information:

(i) name of the Respondent;
(ii) ITS name and number;
(iii) name and number of the sub-category that the product has been tendered into; and
(iv) product code and description.

k. All samples submitted will be disposed of upon completion of the evaluation process unless collection or return instructions are supplied with each sample. Samples to be returned will be at Respondent's cost.

l. For samples to be returned, Respondents are to include instructions with the samples with the following:

(i) clear instructions to indicate if the samples are to be collected from HPV or are to be sent back at the Respondent's cost. For samples that are to be sent back, instructions are to include the freight account or 'con note', an address print out and any necessary paperwork that is to be used by HPV to enable the return to occur.

m. Samples are to be sent to the following address:

Attention to: David Nguyen
HPVITS2019-019
Health Purchasing Victoria
Level 34, Casselden Place, 2 Lonsdale Street
Melbourne, VIC 3000

n. All samples are to arrive at the above address **before** the Tender Closing Date and Time, unless otherwise stated.

5 Definitions

a. For the purposes of this tender, the following terms shall adopt the given definitions.

TERM	DEFINITION
Agreement	A contract entered into by HPV and a Respondent for the provision of goods and associated services. Comprises of the General Conditions, and all Schedules, Annexures of any kind and any attachments.
ARTG	Australian Register of Therapeutic Goods under the control of TGA
Business day	Any weekday not gazetted as a public holiday in Melbourne, Victoria.
GS1	Global Standards One
GTIN	Global Trade Identification Number
HPV	Health Purchasing Victoria
ITS	Invitation To Supply
May	Indicates an optional element; it is at the Respondent's discretion to either meet or not meet this element, and failure to meet this element will not have an impact during evaluation.
Must	Indicates a mandatory requirement; failure to meet this requirement will result in the submission being eliminated from further consideration.
NPC	National Product Catalogue.
Participating Health Services (PHS)	Public Hospitals and other Health or Related Services, as those terms are defined in Section 3 of the Health Services Act 1988 (Vic).
Respondent	Any person, company or organization representing to this ITS and, unless the context otherwise requires, includes those who may access the ITS for the purpose of submitting a Tender.
Shelf life	The date indicator listed on products, whether it is listed as Best Before, Use By or another term.
Should	Indicates a highly desirable element; unless justifiable reason exists, not meeting this element may impact evaluation.
Single use	A device that is intended to be used on an individual patient, during a single procedure, and then discarded.
Single patient use	A device that is intended to be used on an individual patient.. (Source: TGA, Regulation of the Re-Manufacture of Single Use Medical Devices).
SLA	Service Level Agreement.
TGA	Therapeutic Goods Administration.
TRW	Tender Response Worksheet.

TERM	DEFINITION
Will	Indicates an anticipated future condition or requirement to be met.
VPC	Is the central repository of products and pricing information available in a single accessible location. The VPC contains products that are HPC contracted, as well as other non-contracted products that suppliers have published via the GS1 hosted National Product Catalogue.
VPCS	Provides an online user interface for health services users to access the VPC information directly from their HPV website account. It provides quick and easy navigation for functions such as searching, filtering, exporting, comparing and reporting of its contents.

B Service, Delivery and Support

1 Delivery

a. Examination and Surgical Gloves products must 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. Except where there is evidence of inappropriate handling by the receiving Participating Health Services, all damaged or broken products and equipment must be replaced free of charge

c. All deliveries are bound per the Draft Agreement, Part 7 – Acceptance and Rejection of Goods.

2 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. Respondents are to be able to receive and action urgent deliveries.

c. Urgent deliveries should be received by Participating Health Services within the shortest possible timeframe. This should be within **24 hours** from the receipt of order.

3 Training

a. Upon request by a Participating Health Service, successful Respondents must deliver a training package and/or training materials, at no cost to participating health services, to the clinicians in their hospital environment. This is to facilitate the introduction of the Examination and Surgical Gloves contract.

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
(iv) training materials.

c. If requested by a PHS, successful Respondent must provide an education plan detailing how they will provide training to nominated staff. Note that the number of staff involved in training may vary greatly between PHS.

d. Successful Respondent must ensure that the following is available to PHS (in either hard-copy or electronic format):

(i) the credentials of any staff who would be providing support in Victoria;
(ii) the hours of availability for support;
(iii) the geographical area covered by the support (if support is available on-site); and
(iv) the details of educational and/or support materials available to clinicians.

e. All training regimes must be implemented and include appropriate levels of training to meet Workplace Health & Safety standards as required by The Victorian WorkCover Authority.

4 Customer Service and Support

a. The successful Respondent must be able to deliver prompt customer service and support to Participating Health Services.

b. The successful Respondent will nominate at least one Representative as the key account manager to provide the support and to work closely with the PHS and HPV.

c. 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; and
(v) representatives are required to have a valid Police Check and Working with Children Check for the Health Services'.

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

e. 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, Infection Prevention Manager, Supply Managers);
(iv) providing on-site clinical support during cases (if requested);
(v) providing informational materials; and
(vi) providing education and in-service training upon request.

f. Details of Help Desk support, including the toll-free number, the geographical area covered by the support, and the hours available

5 Warranty

a. All reusable products covered in this ITS are to be warranted for a minimum of twelve (12) months from the delivery date for normal use.

b. Where unopened, all consumable (single use) products are to be warranted up to the marked up expiry date. Where opened, all consumable (single use) products are warranted to be free of defects and fit for purpose.

c. Upon request, the successful Respondent must provide information (printed or electronic) explaining product warranty in plain language.

d. It is desirable that the Products can be used with the manufacturer's and non-manufacturer's equipment and software, and that the manufacturer's warranty is not adversely impacted.

Repairs and Replacements under Warranty

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

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

g. 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.

6 Service Level Agreement

a. Successful Tenderers shall enter into a Service Level Agreement (SLA) with individual contract users upon request. The SLA shall 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, education and training; and
(iv) communication arrangements for product recall and safety alert information.

b. The SLA will be in addition to the Agreement between a successful Tenderer 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.

C General Requirements

1 Standards and Compliance

a. All items offered must comply with relevant Australian Standards (or their equivalent International Standards). Please refer to Appendix 2 - Australian and International Standards.

b. All items 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.

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

Latex Content

d. In the relevant columns of the Tender Response Worksheet, Tenderers shall identify the presence of natural rubber latex in each product tendered (including any accompanying packaging).

Preference will be given to items that are latex-free, unless otherwise stated.

DEHP Content

e. In the relevant column of the Tender Response Worksheet, Tenderers shall identify the presence of DEHP for each product tendered.

HPV is committed to providing DEHP-free product options in each category, wherever possible.

2 Packaging and Labelling

a. Products must be packaged to retain the structural integrity of the enclosed product.

b. Products will be packaged in a manner that protects the contents from contamination during transportation, storage and handling.

c. All labels must comply with the Therapeutic Goods Order No. 37: General Requirements for Labels for Therapeutic Goods.

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

e. It is a requirement for individual product packaging to include (where applicable):

(i) Whether all components of the product are sterile or stipulating any non-sterile components;
(ii) whether the product (or packaging) contains latex or is latex-free; and
(iii) tracking labels.
(iv) indication of suitability for chemotherapy and chemical permeation

3 Recall Process

a. All recalls must be managed in line with the *Uniform Recall Procedure for Therapeutic Goods* (2017).

b. Within six (6) months of contract commencement, all recalls and/or hazard alerts will be completed using GS1 Recallnet.

c. Class 1 recalls (as defined by the TGA's *Uniform Recall Procedure for Therapeutic Goods*) must also meet the requirements under section Part 5 – B4 Customer Service and Support. The successful Respondent must be able to deliver prompt customer service and support to Participating Health Services.

d. The successful Respondent will nominate at least one Representative as the key account manager to provide the support and to work closely with the PHS and HPV.

e. 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; and
(v) representatives are required to have a valid Police Check and Working with Children Check for the Health Services'.

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

g. 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, Infection Prevention Manager, Supply Managers);
(iv) providing on-site clinical support during cases (if requested);
(v) providing informational materials; and
(vi) providing education and in-service training upon request.

h. Details of Help Desk support, including the toll-free number, the geographical area covered by the support, and the hours available

i. Warranty

4 Backorders and Discontinued Lines

a. In the event that a product is unavailable for a period of one week, the successful Respondent must contact (at a minimum) the following:

(i) Procurement Officers of all Participating Health Services;
(ii) Supply Manager / Business Managers of all Participating Health Services;
(iii) Clinical Product Advisers, where applicable; and

(iv) HPV.

b. In the event that an item is discontinued, successful Respondents must notify Participating Health Service staff and HPV as soon as possible, but no less than six (6) months before the last date of manufacture.

c. Successful Respondents must inform the affected Participating Health Services and HPV of:

(i) the anticipated timeframe for resolving the issue;
(ii) a backorder report and a list of recommended substituted items to the Participating Health Services and HPV for reference; and
(iii) the availability of an agreed substitute product.

5 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), or most recent version.

6 Superseded Products

a. Where a contracted item is superseded, the new product shall be of the same quality and offered at the same price of the original contracted item. This change request must be submitted to HPV for approval through HPV's Contract Variation process.

7 Shelf Life

a. Products that have an Expiry Date (where applicable) are to have a minimum of six (6) months shelf life on delivery to all PHS.

8 Reference Sites

a. Respondent are required to provide a minimum of three (3) Australian clinical references that are purchasing or have trialled and evaluated the product offered in this submission.

b. Where a product category contains a variety of specific sub-categories, Respondent are to ensure that the clinical references provided are representative of the full range of products tendered.

c. HPV reserves the right to verify this information with health services personnel and seek user feedback as to the acceptability of these products.

d. Respondent should not nominate a referee without their express permission.

D Product Specifications

1 Product Specification and Product List

a. All gloves shall be powder free.

b. Dispenser boxes for all gloves shall:

- Be sufficiently robust to protect the contents
- Retain their shape and structure under normal conditions of storage and use
- Be clearly labelled with the type and size of the gloves

c. Preference will be given to gloves packed in dispenser boxes with the size clearly visible when the box is sitting on a flat surface and/or located within a wall-mounted dispenser.

d. Comply with the TGA labelling & packaging regulatory framework

2 Category Specifications

a. A range of Examination and Surgical Glove is required to meet clinical needs for treatment of patients across Victorian Public Health Services.

Category 1 - Examination Gloves

A full range of single use examination gloves is required to meet clinical needs.

Mandatory Criteria

Non sterile examination gloves shall be packaged in dispenser boxes in a manner that facilitates the removal of single gloves individually.

Tenderers please note that PVC gloves are not included in the scope of this tender.

Sensitivities/Allergies

Where tendered examination gloves are claimed to be recommended for users with sensitive skin, 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

Cytotoxic Drugs

Where examination 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

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 injectable cytotoxic agents.

Gloves recommended for use during preparation and administration of cytotoxic drugs shall be of sufficient length to cover the elasticised cuffs of gowns or coveralls worn by the operator.

Due to the safety link between purple and cytotoxic drugs, examination gloves that are purple in colour but are not recommended for use during the preparation and administration of chemotherapy will not be accepted.

Product Description

For each examination glove offered, Tenderers shall advise the following information in the Product Description of the Tender Response Worksheet:

- Brand name

- Sterile or non-sterile
- Material (e.g. Non latex)
- Size (e.g. small)
- Glove colour (e.g. blue)
- Cuff length:
    - Standard cuff (min. length 220mm)
    - Long cuff (approx. length 280mm)
    - Extra long cuff (approx. length 485mm)
- Cuff beaded (where applicable)
- Ambidextrous or anatomically shaped
- External finish (e.g. smooth, textured)
- Textured fingertips (where applicable)

Additional Information

For each examination glove offered, Tenderers shall advise the following information in the relevant column of the Tender Response Worksheet:

- Glove thickness in millimetres at the:
    - Finger
    - Palm
    - Cuff
- If the:
    - Glove is recommended for the preparation and administration of cytotoxic agents
    - Glove is recommended for users with sensitive skin
    - Tenderer has the ability to barcode individual packaging
    - Glove is safe for food preparation (HACCP Food Safety Standard)
    - Glove meets the requirement of EN ISO 374 for chemical permeation

For each examination glove dispenser box offered, Tenderers shall advise the following information in the relevant column of the Tender Response Worksheet:

- The dimensions of the dispenser box in centimetres

- If dispenser boxes are colour-coded for size
- The position of labelling for size (e.g. front face, short side, long side)

Category 2 - Surgical Gloves

A full range of sterile, anatomically-shaped, single-use surgical gloves is required to meet clinical needs.

Mandatory Criteria

Surgical gloves shall be peel packaged in pairs, to facilitate aseptic removal and donning.

Pairs of surgical gloves shall be packaged in dispenser boxes.

Sensitivities/Allergies

Where tendered surgical gloves are claimed to be recommended for users with sensitive skin, 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

Cytotoxic Drugs

Where surgical 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

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 injectable cytotoxic agents.

Gloves recommended for use during preparation and administration of cytotoxic drugs shall be of sufficient length to cover the elasticised cuffs of gowns or coveralls worn by the operator.

Due to the safety link between purple and cytotoxic drugs, surgical gloves that are purple in colour but are not recommended for use during the preparation and administration of chemotherapy will not be accepted.

Product Description

For each surgical glove offered, Tenderers shall advise the following information in the Product Description of the Tender Response Worksheet:

Single gloving system:

- Brand name
- Type of material (e.g. Non latex)
- Size (e.g. 7)
- Colour (e.g. green)
- Cuff length:
    - Standard cuff (min. length 250mm)
- Cuff beaded (where applicable)
- External finish (e.g. smooth, textured)
- Inner surface coating (e.g. polymer)
- Whether the glove is an under or over glove
- Glove thickness in millimetres for standard, thin and thick:
    - Finger
    - Palm
    - Cuff

For double gloving system (both under and over glove):

- Brand name
- Type of material (e.g. Non latex)
- Size (e.g. 7)
- Colour (e.g. green)
- Cuff length:
    - Standard cuff (min. length 250mm)
- Cuff beaded (where applicable)
- External finish (e.g. smooth, textured)
- Inner surface coating (e.g. polymer)
    - Glove thickness in millimetres for standard, thin and thick:

- Finger
- Palm
- Cuff

Additional Information

For each surgical glove offered, Tenderers shall advise the following information in the relevant column of the Tender Response Worksheet:

- Glove thickness in millimetres at the:
  - Finger
  - Palm
  - Cuff
- If the:
  - Glove is recommended for the preparation and administration of cytotoxic agents
  - Glove is recommended for users with sensitive skin
  - Tenderer has the ability to barcode individual packaging

For each surgical glove dispenser box offered, Tenderers shall advise the following information in the relevant column of the Tender Response Worksheet:

- The dimensions of the dispenser box in centimetres
- If dispenser boxes are colour-coded for size
- The position of labelling for size (e.g. front face, short side, long side)

Category 3 - Dispensers for Examination and Surgical Gloves

A range of glove dispensers is required to facilitate the storage and availability of examination and surgical gloves in user areas.

Mandatory Criteria

Glove dispensers shall be:

- Constructed so that difficult-to-clean corners are minimized
- Non-porous, smooth, and capable of being easily cleaned
- Sufficiently robust to withstand normal wear and tear

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

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

Product Description

For each glove dispenser offered, Tenderers shall advise the following information in the Product Description of the Tender Response Worksheet:

- Brand name
- Dispenser:
    - Wall mountable or other (e.g. bench top, trolley)
        - Method of fixation (where applicable)
    - For examination or surgical gloves
- Dimensions in centimetres
- Type of material (e.g. plastic)
- Colour
- The number of tiers/capacity.

Additional Information

Tenderers shall advise in the relevant column of the Tender Response Worksheet, the compatible dispenser/s for their tendered range of gloves.

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.

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

Appendices

Appendix 1 - Product List

Product Category	Product Subcategory
01- 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
02- Surgical Gloves	02.01 Surgical gloves, latex, standard thickness
	02.02 Surgical gloves, latex, thin thickness
	02.03 Surgical gloves, latex, thick thickness
	02.04 Surgical gloves, non latex, standard thickness
	02.05 Surgical gloves, non latex, thin thickness
	02.06 Surgical gloves, non latex, thick thickness
	02.07 Surgical gloves, under gloves, latex, standard thickness
	02.08 Surgical gloves, under gloves, latex, thin thickness
	02.09 Surgical gloves, under gloves, latex, thick thickness
	02.10 Surgical gloves, under gloves, non latex, standard thickness
	02.11 Surgical gloves, under gloves, non latex, thin thickness
	02.12 Surgical gloves, under gloves, non latex, thick thickness
	02.13 Surgical gloves, double gloving system, latex
	02.14 Surgical gloves, double gloving system, non latex
03 - Glove Dispensers	03.01 Dispensers for examination gloves

Appendix 2 - Australian and International Standards

All Examination and Surgical Gloves offered shall comply with and be tested to at least one of the following applicable standards:

- All products should be TGA & ARTG approved
- ISO 10282:2014 Single-use sterile rubber surgical gloves – Specification
- ISO 11193-1:2008 Single-use medical examination gloves - Part 1: Specification for gloves made from rubber latex or rubber solution
- AS/NZS 4011.1:2014 Single-use examination gloves – Specification for gloves made from rubber latex or rubber solution
- AS/NZS 4011:2:2014 Single –use medical examination gloves – Part 2: Specification for gloves made from poly(vinyl chloride)
- AS/NZS 4179:2014 Single-use sterile surgical rubber gloves – Specification
- ASTM D3577 Standard Specification for Rubber Surgical Gloves
- ASTM D3578 Standard Specification for Rubber Examination Gloves
- ASTM 6978 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
- ASTM D6319-2015 Standard Specification for Nitrile examination Gloves for Medical application
- EN 455 Parts 1 to 4 2000 to 2009 Medical gloves for single use

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

- WorkSafe Victoria Handling Cytotoxic Drugs in the Workplace 2003
- Occupational Health and Safety Act 1985
- ACORN Standards 15th edition.

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

- EN ISO 374:2003 AS/NZS 2161.10:2005 Chemical Permeation
- HACCP Food Safe Certification

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

HPV reserves the right to request further testing:

- Where a product quality issue is identified during the contract
- Should an option period be exercised at the end of the contract principal period.

In the event that further testing is required, HPV reserves the right to remove products from contract, should a successful Tenderer refuse to retest products to prove compliance to applicable standards.

Guidelines and Other References

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

- NHMRC (2010), Australian Guidelines for the Prevention and Control of Infection in Healthcare, Commonwealth of Australia.
- Therapeutic Goods Administration (1991), Therapeutic Goods Order No. 37: General Requirements for Labels for Therapeutic Goods.
- Therapeutic Goods Administration (2017), Uniform Recall Procedure for Therapeutic Goods, Commonwealth of Australia.
- Therapeutic Goods Administration (2011), Australian Regulatory Guidelines for Medical Devices.