Invitation to Supply

ITS Number:	HPVITS2021-015
ITS Name:	Respiratory Products
Closing Date and time:	XXX 14:00 AEST

HEALTH PURCHASING VICTORIA

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 organisations as follows as outlined in Part 5 of this ITS.

2 Scope

a. The scope of this ITS includes:

- Respiratory products and patient circuits used in most clinical settings, including:
  - all critical care areas, from neonate to adult
  - anaesthetics
  - general wards and departments
- Products that are compatible with a range of equipment systems, including:
  - ventilators (mechanical, CPAP, BiPAP, acute care)
  - anaesthetic machines
  - suction systems
  - humidification systems
  - oxygen therapy systems

3 Product Categories

a. The categories of Respiratory Products required under this ITS include:

Category Number	Category Name
1	Oxygen Face Masks
2	Anaesthesia/Resuscitation Face Masks
3	Non-Invasive Ventilation Interfaces

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Category Number	Category Name
4	Nasal Cannulae
5	Oxygen Tubing
6	Nebulisers
7	Breathing Circuits and Accessories
8	Respiratory Filters
9	Gas Sampling Lines and Co2 Monitoring
10	Catheter Mounts and Connectors
11	Rebreathing Bags
12	Oropharyngeal Airways (Guedel)
13	Nasopharyngeal Airways
14	Endotracheal Tubes
15	Intubation Stylets, Airway Catheters and Guides
16	Laryngeal Mask Airways
17	Tracheostomy Tubes
18	Yankauer Suction Devices
19	Suction Catheters
20	Closed Ventilation Suction Systems
21	Suction Tubing
22	Closed Wall Suction Systems
23	Manual Resuscitators
24	Laryngoscope Blade
25	Asthma Spacers

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

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

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

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4 Direct match and alternatives

a. Responders are to list a direct match to the part number listed on the Tender Response Worksheet.

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

5 Price review

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

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

(ii) response to pricing review must be submitted in the format requested by HPV 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. The price review will be based on the variation (increase or decrease) in imported content of the contracted products. The Contractor must provide evidence of the cost variation to HPV.

c. Price movements can only be initiated on the following conditions:

(i) The monthly average movement in the AUD exchange rate (reference to RBA) of the last twelve months prior to each option period, and

(ii) The price review is capped to 3%.

d. HPV reserves the right to negotiate price review outcomes with the successful Contractor.

6 Award scenario

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

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

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

7 Conditional Acceptance

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

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(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 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.

8 Product Conditions

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 Duplication

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

- HPVC2014-015 Respiratory Products

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

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.

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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:

a) Not labelled as per d above; or

b) Is incomplete as to c.

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

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

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a. Service, delivery, and support

1 Delivery

a. Respiratory Products 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 – 9 Acceptance and Rejection of Deliverables.

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. 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.

3 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.

4 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.

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5 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

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 24 hours a day OR during business hours.

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 (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.

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

6 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 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.

7 Key Performance Indicators

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

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8 Reporting

a. Refer to Draft Deed of Standing Offer Agreement – clause 13.4 and Schedule 4 – Reporting Guidelines and Participating Health Services.

9 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 43 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.

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b. General Requirements

1 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. HPV 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.

2 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.

3 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 5 - 6 Warranty, where applicable.

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4 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) 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.

5 Backorders and Discontinued Lines

(i) In the event that a product is unavailable for more than 5 Business Days from the intended date of supply, the successful Respondent must contact (at a minimum) the following:

- the Clinical Product Advisor (where applicable);
- the Nurse Unit Manager;
- procurement officers of all Participating Health Services; and
- HPV

(ii) Successful Respondents must inform the affected Participating Health Services and HPV of:

- the anticipated timeframe for resolving the issue
- the availability of an agreed substitute product.

(iii) In an anticipated stock outage, successful Respondents are to notify the Health Service and HPV of the estimated timeframe of the outage, availability of an agreed substitute product and recovery action plan within 48 hours.

(iv) 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.

6 Superseded Products

(i) Where a contracted item is superseded by a new product, the new product must be offered at the price of the original item, and the price of the original item must be reduced until it has been phased out.

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c. Product Specifications

1 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).

2 Reusable Devices

(i) For reusable products, the following information must be readily available to all Participating Health Services in electronic format:

- instructions for cleaning, sterilisation and reuse
- warranty information.

3 Category Specifications

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

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Category 1 - **Oxygen Face Masks**

A range of single-patient use, clinically clean latex-free, oxygen & aerosol face masks is required including:

a) a full range of sizes from neonates to adults

b) aerosol masks in elongated and non-elongated

c) low, medium, high and variable/multiple concentration oxygen face masks

d) for connection to a humidification system

e) tracheostomy masks, direct tracheostomy connection and face tents

f) with and without oxygen tubing

g) masks with access for end tidal CO2 sampling.

Note: Oxygen face masks with oxygen tubing must also comply with the specifications for Category 5 (Oxygen Tubing).

Note: Aerosol masks with a nebulizer are to be tendered in category 6.02

The body of each face mask must:

1) be malleable

2) fit under the patient's chin to fit effectively around the face

3) have no rough or sharp edges

4) incorporate:

   i. a securely fixed inlet adaptor connected under the nosepiece

   ii. a retaining latex-free elasticised strap that can be easily repositioned to hold the mask firmly in place.

If the oxygen mask includes a nose clip, then the nose clip must be securely attached to the body of the mask.

For variable/multiple oxygen concentration masks, instructions for use (including assembly and the method of varying the FiO2) must be included on individual item packaging or as a package insert.

Preference may be given to variable/multiple oxygen concentration masks that offer the widest range of FiO2 and total gas flow.

Note: Suppliers are to state if any of their products have a unique connection or dedicated consumable. For example aerosol mask to a specific device. If there are specific CO2 connection cables for CO2 monitoring, state which device and mask they match.

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Category 2 - **Anaesthesia/Resuscitation Face Masks**

A range of clinically clean latex-free face masks is required to meet clinical needs for anaesthesia, resuscitation and first responders, including:

a) a full range of sizes from neonates to adults

b) single use and reusable

c) scented and unscented

d) round and anatomically shaped

e) with and without:

i. an inflatable cushion seal

ii. colour-coded sizes

iii. a range of materials.

Anaesthesia/resuscitation face masks must have no rough or sharp edges.

Reusable anaesthesia/resuscitation face masks that have a cushion seal must incorporate an inflation valve to allow reinflation of the cushion.

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Category 3 - **Non-Invasive Ventilation Interfaces**

A range of clinically clean, latex-free, non-invasive ventilation interfaces is required for use in a variety of clinical settings including ED, ICU, acute, subacute, rehabilitation and perioperative:

a) a full range of sizes from neonates to adult

b) for non-invasive ventilation interfaces

c) full face, nasal masks, nasal pillows, nasal prongs, headgear and mouthpiece ventilation devices

d) single use and reusable

e) vented and non-vented

f) with and without:

i. inflation port

ii. expiratory port

iii. anti-asphyxiation valves

g) a quick release mechanism for rapid removal during an emergency

h) any replacement parts or individual components that are sold separately (including headgear).

i) Products for prevention and management of interface related side effects i.e. barriers, pads and straps.

Non-invasive ventilation masks must have no sharp or rough edges.

Non-invasive ventilation masks must be permanently labelled with sizing information.

1) Each interface must incorporate a strap; the strap must be removable if it contains latex.

2) Where masks require assembly, kits must include assembly information as an insert.

3) Kits must not have any latex content in the kit packaging.

Upon request by Participating Health Services, successful Respondents must provide a list of compatible parts and equipment for connection and use.

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Category 4 - Nasal Cannulae

A range of single-patient use, clinically clean latex-free, non-humidifier nasal cannulae (nasal prongs) in delivering oxygen and/or medical air is required including:

a) a full range of sizes from neonates to adults

b) straight, curved and flared prongs

c) with or without:

   i. end tidal CO2 monitoring, with or without filters

d) with tubing attached

e) with 'over-the-head' or 'around-the-ears' methods of attachment

f) nasal O2 catheters

Note: Nasal cannulae with tubing attached must also comply with the specifications for Category 5 (Oxygen Tubing).

Nasal prongs must:

1) be smooth, soft and pliable to maximise patient comfort

2) have no sharp or rough edges.

The body of the cannulae must be malleable and fit under the patient's nose to allow prongs to sit within the nostrils.

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Category 5 - **Oxygen Tubing**

A range of single-patient use, clinically clean latex-free, flexible oxygen tubing is required, including:

a) for attachment to oxygen therapy and aerosol therapy masks

b) pre-cut lengths and rolls of tubing

c) with and without female connectors to fit standard oxygen delivery equipment

d) corrugated tubing, with integral cuffs

e) smooth bore, bubble-type and crush-resistant tubing.

Note: Pre-cut oxygen tubing must:

1) be a minimum of two metres in length

2) incorporate a connector that can attach to a standard oxygen nipple connection

3) be able to deliver at least 15 litres of oxygen per minute without detachment.

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Category 6 - Nebulisers

A range of clinically clean latex-free, single-patient use, non-electrical nebulisers is required to meet clinical needs. This includes:

a) with and without oxygen tubing

b) individual components and kit

c) Please state the:

i. maximum tilt angle that the nebulizer will effectively perform

ii. particle size

iii. residual volume (millilitres)

Note: Nebulizers with tubing attached must also comply with the specifications for Category 5 (Oxygen Tubing).

Where oxygen tubing is provided, it must:

1) be a minimum of two metres in length

2) incorporate a connector that can attach to a standard oxygen nipple connection

3) be able to deliver up to 15 litres of oxygen per minute without detachment.

Preference may be given to kits that have the recommended gas flow for optimal performance included as a package insert.

Upon request by Participating Health Services, successful Respondents must provide the following information (in electronic format):

I. the useful life for each nebulizer (considering the frequency of use)

II. cleaning instructions for when the nebulizer is reused on the same patient

III. drug deposition test results

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Category 7 - Breathing Circuits and Accessories

A range of individually packaged latex-free breathing circuits of varying lengths is required, including: a full range of sizes from neonates to adult for use in acute care environment including ED, ICU, acute, subacute, rehabilitation and perioperative:

a) for use in anaesthesia, to suit a wide range of anaesthetic delivery systems
b) for ventilation in an inpatients setting, to suit a range of ventilators

Circuit configurations to consist of:

1) Non-heated and heated
2) single, dual, and dual with limb
3) analgesic circuits
4) fixed and extendable
5) smooth and corrugated bore
6) with and without:
    I. Y-piece
    II. rebreathing bag
    III. bacterial / viral filter, HME or combined HME bacterial/viral filters, HEPA and non-HEPA
    IV. other optional components (for example, mouth pieces and face masks, where applicable)

Note: For proprietary consumables product that is available from one supplier and fits/use with one only brand of device. The device must be awarded in an existing HPV Equipment contract.

- **Please ensure to include at the start of the product description the brand and model to which your proprietary consumables fit.**

Note: Airway tubing will consist of single-limb tubing and will be in heated or non-heated breathing circuits.

Note: Breathing circuits with a bacterial/viral filter must also comply with the specifications for Category 8 (Respiratory Filters).

Note: Breathing circuits with a rebreathing bag must also comply with the specifications for Category 11 (Rebreathing Bags).Breathing circuits must: have a smooth transition of the inside surface (between the body of the breathing tube and the ends) to minimise gas turbulence

- be made of materials that:
    - are compatible and resistant to deterioration
    - have low absorption and permeability with substances that they may contact during the intended use.

Preference may be given to kits/breathing circuits that have the contents printed on the packaging or included as a package insert.

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Category 8 - **Respiratory Filters**

A range of single-patient use respiratory filters is required, including:

a) a full range of sizes from neonates to adults

b) heat and moisture exchangers (HME), bacterial/viral filters or combined HME bacterial/viral filters

c) for use on spontaneously breathing and mechanically ventilated patients

d) sterile and clinically clean

e) with and without:

   i. accessory ports

   ii. connectors

   iii. catheter mounts

   iv. right angles

   v. elbow

   vi. tubing.

f) for each tendered product, state:

   i. viral filtration efficiency

   ii. bacterial filtration efficiency

   iv. resistance at initial flow of 30 L/min

   v. for HME filters, moisture loss at Vt 250 mL

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Note: Respiratory filters with oxygen tubing must also comply with the specifications for Category 5 (Oxygen Tubing).

Note: Respiratory filters with gas sampling tubing must also comply with the specifications for Category 9 (Gas Sampling Lines).

Upon request by Participating Health Services, successful Respondents must provide the following information (in electronic format):

1) physical dimensions in millimetres
2) recommended flow rate in litres
3) recommended range of tidal volume in millilitres
4) dead space
5) moisture output (in relation to tidal volume) in milligrams of H2O per litre
6) resistance to flow in centimetres of H2O at litres per minute
7) recommended maximum period of continuous use before disposal (in hours)
8) compliance (millilitres per kPa-1)
9) Preference will be given to tethered caps.

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Category 9 - Gas Sampling and C02 Monitoring

A range of single-use latex-free and consumable gas sampling lines for use during ventilation is required, including:

a) a full range of sizes from neonates to adults

b) for use with:

    a. end tidal CO2 monitoring

    b. anaesthetic agent monitoring

c) with male/male and male/female luer lock connectors

d) with and without:

    a. filter

    b. sampling port

    c. sampling cuvette

e) single and multiple channels

f) a range of materials

g) a range of lengths and diameters to suit a wide range of capnographs and gas spectrometers.

h) manufacturer maximum use time

i) clinically clean or sterile

Note: Gas sampling lines with respiratory filters must also comply with the specifications for Category 8 (Respiratory Filters), where applicable.

Where filters are incorporated, they must protect the sampling lines from moisture and bacterial contamination.

Note: Suppliers who tender products for this category will be required prior to the end-date of this contract to retender in an alternative contract HPVC20XX-021 - Monitoring Products.

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Category 10 - Catheter Mounts and Connectors

A range of latex-free single-use and reusable catheter mounts is required, including:

a) a full range of sizes from neonates to adults

b) for connection to breathing circuits

c) sterile and clinically clean

d) straight and angled

e) with and without:

   i. suction port

   ii. swivel elbow

   iii. gas sampling access

   iv. metered dose elbow

f) standard and extendable

g) a range of materials

h) additional components.

A range of latex-free single-use and reusable connectors is required, including:

1) a full range of sizes from neonates to adults

2) for connection to breathing circuits

3) sterile and clinically clean

4) straight and angled

5) with and without:

   I. suction port

   II. single and double swivel elbow(s)/connector(s)

   III. gas sampling access

   IV. luer ports

   V. port caps

   VI. metered dose elbow

6) a range of materials

7) additional components.

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Note: If a catheter mount is attached to a respiratory filter, then this product must be offered in Category 8 (Respiratory Filters).

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Category 11 - **Rebreathing Bags**

A range of latex-free clinically clean single-use and reusable rebreathing bags is required, including:

a) a full range of sizes from neonates to adults

b) specify volume in litres

c) plain and assembled neck

d) open- and closed-ended

e) standard and anti-static

f) a range of materials.

g) soft or hard ferrule

Rebreathing bags must be manufactured from materials that are compatible with clinical concentrations of anaesthetic agents, and must have low absorption and permeability.

Successful Respondents must provide (in electronic format) compliance data for rebreathing bags.

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Category 12 - **Oropharyngeal Airway (Guedel)**

A range of latex-free individually wrapped, single-patient use oropharyngeal airways is required to meet clinical needs. This includes:

a) a full range of sizes from neonates to adults

b) state length in millimetres

c) sterile and clinically clean

d) with colour coding.

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Category 13 - **Nasopharyngeal Airway**

A range of latex-free individually wrapped, single-patient use nasopharyngeal airways is required, including:

a) a full range of sizes from neonates to adults

b) sterile and clinically clean.

Nasopharyngeal airways must:

1) specify material of build

2) specify size in millimetres and French gauge

3) be manufactured from soft, compliant materials with a smooth finish (including rounded edges to minimise insertion trauma and maximise patient comfort)

4) be kink resistant

5) incorporate a flange at the external end.

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Category 14 - **Endotracheal Tubes**

A range of latex-free sterile endotracheal tubes is required, including:

a) a full range of sizes from neonates to adults including extra length

b) single use and reusable

c) standard, for use in laser surgery, reinforced, preformed and others (e.g. for endobronchial intubation, intended for left or right bronchus)

d) PVC and silicone

e) cuffed and uncuffed

f) for short- and long-term intubation

g) where applicable:

   i. North facing or south facing

   ii. Murphy eye, Magill

   iii. low-pressure cuff

   iv. subglottal cuff

h) kit presentations.

Endotracheal tubes must:

1) be packaged individually with a connector included

2) incorporate a radio-opaque line extending the length of the tube.

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Category 15 - Intubation Stylets, Airway Catheters and Guides

A range of latex-free flexible intubation stylets, airway catheters and guides is required, including:

a) to assist intubation in adult, paediatric, infant and neonatal patients (including difficult intubation)

b) a range of:

   i. outer diameter (mm), size (fr) and length (mm)

   ii. tip configuration

c) sterile and clinically clean

d) single use

e) a range of materials

f) with and without graduations

g) hollow and solid lumen

h) additional components

i) individually wrapped and bulk packaged.

Intubation stylets, airway catheters and guides must:

1) have a smooth surface and atraumatic tip, and

2) incorporate an outer coating or surface that helps reduce friction between the stylet and tube.

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Category 16 - **Laryngeal Mask Airways**

A range of latex-free laryngeal mask airways is required, including:

- a full range of sizes from neonates to adults
- single use and reusable
- standard and reinforced
- silicone and PVC
- with and without:
    - gastric access tube
    - introducer
    - inflation pressure indicator.

For reusable laryngeal masks, successful Respondents must provide the following information (in electronic format) to Participating Health Services upon request:

- instructions for cleaning, sterilisation and reuse
- the recommended number of uses and reuse conditions for a single laryngeal mask airway
- the recommended process for tracking the use of each laryngeal mask airway.

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Category 17 - Tracheostomy Tubes

A range of latex-free sterile patient use tracheostomy tubes for acute care is required, including:

a) a full range of sizes from neonates to adults

b) for surgical and percutaneous introduction

c) for establishing an airway in an emergency situation

d) cuffed and uncuffed

e) fenestrated and non-fenestrated

f) standard and reinforced

g) with and without:

   i. adjustable flange

   ii. integral suction port

   iii. inner cannula

   iv. various fasteners

h) percutaneous insertion kits with and without tracheostomy tube

i) spare and additional components, including but not limited to:

   I. speaking valves with colour-coding

   II. inner cannulae

   III. plugs

   IV. sponges

j) emergency cricothyrotomy kits.

Note: For the purposes of this ITS, customised tracheostomy tubes that are manufactured to meet individual patient needs are considered out of scope.

- Tracheostomy tubes with air-filled cuffs must incorporate a self-sealing inflation valve.
- The contents of tracheostomy kits must be printed on the label of individual kits.
- Diagrammatic details of tube dimensions should be provided either on or in product packaging.

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Category 18 - Yankauer Suction Devices

A range of latex-free sterile, single-patient use Yankauer suction devices is required, including:

a) a full range of sizes from neonates to adults

b) respondents must specify the tip type e.g. open tip, rose tip, sump tip

c) vented or non-vented

d) single-wrapped and double wrapped

Yankauer suction devices must:

1) be a one-piece construction

2) have a smooth, rounded eye

3) have no sharp or rough edges

4) have a male end that is permanently fixed to the shaft and that allows a secure attachment with the connectors on standard suction tubing.

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Category 19 - **Suction Catheters**

A range of latex-free sterile, single-use suction catheters is required, including:

a) a full range of sizes from neonates to adults

b) straight and left angled

c) a range of tip configurations

d) with and without depth markings along the shaft

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Category 20 - Closed Ventilation Suction Systems

A range of latex-free single-patient use closed ventilation suction systems is required to facilitate the suctioning of patients receiving mechanical ventilation. This includes:

a) a full range of sizes from neonates to adults

b) for connection to endotracheal tubes and tracheostomy tubes

c) sterile

d) a range of tip configurations

e) with and without:

   i. one-way irrigation port

   ii. swivel connection

   iii. T-piece

   iv. metered dose inhaler (MDI) connection

   v. spare and additional parts for multi-port access

   vi. for various periods of continuous use.

Ventilation suction systems must incorporate:

1) a tactile sleeve to enhance practitioner control during the suction procedure

2) a thumb valve

3) depth markings on the suction catheter.

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Category 21 - **Suction Tubing**

A range of latex-free single-use suction tubing is required, including:

a) rolls and pre-cut lengths

b) with and without integral connectors

c) kink-resistant, bubble, wide-bore and heavy-duty types

d) sterile or clinically clean

e) single and double-wrapped sterile pre-cut tubing lengths

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Category 22 - Closed Wall Suction System

A range of latex-free closed suction systems for connection to wall suction outlets is required, including:

- a range of canister/container volumes with compatible liners
- with and without:
    - shut off valves
    - filters
- relevant hardware to effectively set up the system
- additional components and accessories.

Note: For the purposes of this ITS, suction systems that do not incorporate a disposable collection liner are considered out of scope.

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Category 23 - **Manual Resuscitators**

A range of latex-free manual resuscitators is required, including:

a) a full range of sizes from neonates to adults

b) specify the resuscitator bag volume in litres

c) single-patient use and reusable

d) with and without:

   a. swivel connector

   b. masks

   c. tubing

   d. a connection for attaching a PEEP valve

   e. a pressure release valve

e) manual resuscitators shall be supplied pre-assembled

Manual resuscitators must incorporate:

f) a reservoir bag in litres

g) a low dead-space patient valve assembly.

Paediatric and infant models must incorporate a pressure relief valve to minimise the risk of over-inflation.

For all reusable manual resuscitators offered, respondents must provide cleaning, assembly and testing instructions to Participating Health Services upon request.

Note: tubing must be compliant with Category 5

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Category 24 - **Laryngoscope Blade**

A range of single-use and reusable laryngoscope blades, all-in-one units is required including:

a) standard and specialty blades

b) fibre optic

c) MRI compatible

d) please specify the size and type

Note: Blades should meet ISO7376 green system, so that all blades are interchangeable.

Note: Video laryngoscope blades are out of scope.

For single-use blades, battery and/or globe life must be clearly labelled on the packaging.

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Category 25 - **Asthma Spacers**

A range of latex-free Asthma Spacer is required including:

a) a full range of sizes from paediatrics to adults

b) mouth piece shape ISO standard fitting i.e. 15mmF/22mmM round mouth piece

c) universal inhaler fitting

d) material of build i.e. polypropylene, polycarbonate

e) volume in millilitres

f) cleaning instructions for hospital (if resuable) and home (if single patient use)

Note: Preference will be given to anti-static Asthma Spacers

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Appendices to statement of requirements

Appendix 1 - Product List

Category		Subcategory	
1	Oxygen Face Masks	1.01	Oxygen Face Mask, Medium Concentration
		1.02	Oxygen Face Mask, High Concentration
		1.03	Oxygen Face Mask, Variable/Multiple Concentration
		1.04	Oxygen Face Mask, Aerosol Therapy Mask
		1.05	Oxygen Face Mask, Tracheostomy
		1.06	Oxygen Face Mask, Face Tent
		1.07	Oxygen Face Mask, with CO2 monitoring
2	Anaesthesia/Resuscitation Face Masks	2.01	Anaesthesia/Resuscitation Face Mask, Single Use
		2.02	Anaesthesia/Resuscitation Face Mask, Reusable
		2.03	First Responder Resuscitation Pocket Mask & Shield
3	Non Invasive Ventilation Interfaces	3.01	Non Invasive Ventilation Interfaces, Full Face Masks, Non-vented
		3.02	Non Invasive Ventilation Interfaces, Full Face Masks, Vented
		3.03	Non Invasive Ventilation Interfaces, Nasal Masks & Nasal pillows
		3.04	Non Invasive Ventilation Interfaces, Total Face Masks
		3.05	Non Invasive Ventilation Interfaces, Mouthpiece Ventilation Device
		3.06	Non Invasive Ventilation Interfaces, Single Use, Humidified Nasal cannulae
		3.07	Non Invasive Ventilation Interfaces, Replacement Parts & Accessories including Headgear
4	Nasal Cannulae	4.01	Nasal Cannulae, With Tubing
		4.02	Nasal Oxygen Catheters
		4.03	Nasal Cannula, with CO2 monitoring
5	Oxygen Tubing	5.01	Oxygen Tubing, Smooth Bore, Roll
		5.02	Oxygen Tubing, Smooth Bore, Pre-cut
		5.03	Oxygen Tubing, Bubble-type, Roll
		5.04	Oxygen Tubing, Corrugated, with Integral Cuff, Roll
		5.05	Oxygen Tubing, Crush Resistant, Pre-cut
6	Nebulisers	6.01	Nebulisers
		6.02	Nebulizers & Kits
7		7.01	Heated Breathing Circuit Kits, Single Limb

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	Breathing Circuits and Accessories	7.02	Heated Breathing Circuit Kits, Dual Limb
		7.03	Heated Breathing Circuit Kits - Proprietary Consumables
		7.04	Non Heated Breathing Circuit Kits, Single Limb
		7.05	Non Heated Breathing Circuit Kits, Dual Limb
		7.06	Non Heated Breathing Circuit Kits - Proprietary Consumables
		7.07	Anaesthetic Breathing Circuits, Coaxial, Single use
		7.08	Anaesthetic Breathing Circuits, Dual, Single use
		7.09	Anaesthetic Breathing Circuits, Dual with Limb & Bag, Single use
		7.10	Anaesthetic Breathing Circuits, Coaxial, Reusable
		7.11	Anaesthetic Breathing Circuits, Dual, Reusable
		7.12	Anaesthetic Breathing Circuits, Dual with Limb & Bag, Reusable
		7.13	Aryes T-piece, Single use
		7.14	Breathing Circuit Accessories
		7.15	Anaesthetic Breathing Circuits Accessories
		7.16	Analgesic Breathing Circuits
8	Respiratory Filters	8.01	Respiratory Filter, Heat and Moisture Exchangers (HME)
		8.02	Respiratory Filter, Bacterial/Viral Filter
		8.03	Respiratory Filter, Combined HME/Bacterial/Viral Filter
		8.04	Respiratory Filter, Combined HEPA and HME/Bacterial/Viral Filter
		8.05	Respiratory Filter, HEPA
		8.06	Respiratory Filter, HEPA plus HME
9	Gas Sampling Lines and Co2 Monitoring	9.01	Gas Sampling Lines, Anaesthesia Gases
		9.02	Gas Sampling Lines, Anaesthesia Gases, Water Traps
		9.03	Gas Sampling Lines, CO2 Monitoring lines
		9.04	Gas Sampling Lines, CO2 Monitoring line water traps
		9.05	Gas Sampling Lines, CO2 Monitoring lines, high ambient humidity
		9.06	Gas Sampling Lines, CO2 Airway Adapters
10	Catheter Mounts and Connectors	10.01	Catheter Mounts
		10.02	Connectors
11	Rebreathing Bags	11.01	Rebreathing Bag, Single Use, Closed End
		11.02	Rebreathing Bag, Single Use, Open End
		11.03	Rebreathing Bag, Reusable, Closed End
12		12.01	Oropharyngeal Airways (Guedel), Sterile

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	Oropharyngeal Airways (Guedel)	12.02	Oropharyngeal Airways (Guedel), Clinically Clean
13	Nasopharyngeal Airways	13.01	Nasopharyngeal Airways, Sterile
14	Endotracheal Tubes	14.01	Endotracheal Tube, Uncuffed
		14.02	Endotracheal Tube, cuffed, low volume, high pressure
		14.03	Endotracheal Tube, cuffed, high volume, low pressure
		14.04	Endotracheal Tube, pre-formed, cuffed
		14.05	Endotracheal Tube, pre-formed, uncuffed
		14.06	Endotracheal Tube, Cuffed, Reinforced
		14.07	Endotracheal Tube, Uncuffed, Reinforced
		14.08	Endotracheal Tube, Cuffed, Supraglottic suction
		14.09	Endotracheal Tube, for Endobronchial Intubation (Tubes & Blockers)
		14.10	Endotracheal Tube, Cuffed, for Laser Surgery
		14.11	Endotracheal Tube, Uncuffed, for Laser Surgery
		14.12	Endotracheal Tube, Microlaryngeal
		14.13	Endotracheal Tube, Other
15	Intubation Stylets, Airway Catheters and Guides	15.01	Intubation Stylets, single use, sterile
		15.02	Intubation Stylets, single use, clinically clean
		15.03	Intubation Airway Catheters and Guides, Single-use, sterile
16	Laryngeal Mask Airways	16.01	Laryngeal Mask Airways, Single Use, standard
		16.02	Laryngeal Mask Airways, Single Use, reinforced
		16.03	Laryngeal Mask Airways, Reusable, standard
		16.04	Laryngeal Mask Airways, Reusable, reinforced
		16.05	Laryngeal Mask Airways, Intubation Accessories
17	Tracheostomy Tubes	17.01	Tracheostomy Tube, Cuffed
		17.02	Tracheostomy Tube, Uncuffed
		17.03	Tracheostomy Tube, Reinforced
		17.04	Tracheostomy Tube, Fenestrated
		17.05	Tracheostomy Kit with Tracheostomy Tube
		17.06	Tracheostomy Kit without Tracheostomy Tube
		17.07	Tracheostomy Spare and Additional components - Speaking Valves
		17.08	Tracheostomy Spare and Additional components - Inner Cannulae
		17.09	Tracheostomy Spare and Additional components - Plugs
		17.10	Tracheostomy Spare and Additional components - Sponges
		17.11	Tracheostomy Spare and Additional components - Other

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		17.12	Cricothyrotomy Kits
18	Yankauer Suction Devices	18.01	Yankauer Suction Devices, Sterile, Single-wrapped, Non-Vented
		18.02	Yankauer Suction Devices, Sterile, Single-wrapped, Vented
		18.03	Yankauer Suction Devices, Sterile, Double-wrapped, Non-Vented
		18.04	Yankauer Suction Devices, Sterile, Double-wrapped, Vented
19	Suction Catheters	19.01	Suction Catheter, Straight
		19.02	Suction Catheter, Angled
20	Closed Ventilation Suction Systems	20.01	Close Ventilation Suction System, Single lumen, for Endotracheal Tubes
		20.02	Close Ventilation Suction System, Single lumen, for Tracheostomy Tubes,
		20.03	Close Ventilation Suction System, Double lumen, for Endotracheal Tubes,
		20.04	Close Ventilation Suction System, Double lumen, for Tracheostomy Tubes,
21	Suction Tubing	21.01	Suction Tubing, Pre-cut lengths, Clinically clean, Individually wrapped
		21.02	Suction Tubing, Pre-cut lengths, Sterile, Single-wrapped
		21.03	Suction Tubing, Pre-cut lengths, Sterile, Double-wrapped
		21.04	Suction Tubing, Bulk Rolls, Clinically clean
		21.05	Suction Tubing, Wide bore, Heavy Duty, Pre-cut, Sterile, Double Wrapped
		21.06	Suction Tubing, Bubble, Bulk Rolls
22	Closed Wall Suction Systems	22.01	Closed Wall Suction System, Liner
		22.02	Closed Wall Suction System, Hardware - Canisters
		22.03	Closed Wall Suction System, Hardware - Wall Bracket
		22.04	Closed Wall Suction System, Hardware - Baskets
		22.05	Closed Wall Suction System, Other Components
23	Manual Resuscitators	23.01	Manual Resuscitator
24	Laryngoscope Blade	24.01	Laryngoscope Blade, Fibre-optic, Single use
		24.02	Laryngoscope Blade, Fibre-optic, Reusable
		24.03	Laryngoscope Blade, Fibre-optic, MRI Conditional
25	Asthma Spacers	25.01	Asthma Spacers

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Appendix 2 - Compliance Requirements

Australian Standards, Orders, Legislation and Regulations

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 Respiratory Products may include, but is not limited to:

Standard Number	Standard Name
AS 10993	Biological evaluation of medical devices
AS 1600	Medical equipment - Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment
AS 2488	Resuscitators intended for use with humans
AS ISO 5361	Anaesthetic and respiratory equipment – Tracheal tubes and connectors
AS ISO 5366	Anaesthetic AND respiratory equipment – Tracheostomy tubes AND CONNECTORS
AS/NZS 2496	Breathing attachments for anaesthetic purposes for human use
AS/NZS 4236	Respiratory therapy equipment – Jet nebulizers and jet nebulizer air pumps
AS/NZS 4187	Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities
ISO 10079	Medical suction equipment
ISO 14408	Tracheal tubes designed for laser surgery – Requirements for marking and accompanying information
ISO 17510	MEDICAL DEVICES - Sleep apnoea breathing therapy – MASKS AND APPLICATION ACCESSORIES
ISO 4135	Anaesthetic and respiratory equipment – Vocabulary
ISO 5356	Anaesthetic and respiratory equipment – Conical connectors
ISO 5364	Anaesthetic and respiratory equipment – Oropharyngeal airways
ISO 5367	ANAESTHETIC AND RESPIRATORY EQUIPMENT – BREATHING SETS AND CONNECTORS Breathing tubes intended for use with anaesthetic apparatus and ventilators

Standard Number	Standard Name
ISO 7376	Anaesthetic and respiratory equipment – Laryngoscopes for tracheal intubation
ISO 8836	Suction catheters for use in the respiratory tract
ISO 9360	Anaesthetic and respiratory equipment - heat and moisture exchangers (HMEs) for humidifying respired gases in humans

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

- Therapeutic Goods (Medical Devices) Regulations 2002
- Therapeutic Goods Act 1989

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

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