HealthShare Victoria

Invitation to Supply

ITS Number:	HPVITS2021-005
ITS Name:	Hypodermic Needles and Syringes
Closing Date and Time:	23 June 2021 14:00 AEST/AEDT

HealthShare Victoria

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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:

- Needle and Syringe Program of the Department of Health (DH)
- Other Health Entities

2. Scope

a. The scope of this ITS includes:

(i) Hypodermic Needles and Syringes used in most clinical settings, including:

- all critical care areas, from neonate to adult
- general wards, aged care, and departments
- Community vaccination programs associated with schedule 5 public hospitals

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

- Syringe Drivers

b. The scope of this ITS does not include:

(i) supply of Oral Dispensers;
(ii) supply of Winged Infusion Sets (Scalp Vein Needles);
(iii) supply of Blood Gas Syringes;
(iv) supply of Dental Needles; and
(v) supply of Vascular Access Needles.

3. Product Categories

a. A complete range of Hypodermic Needles and Syringes is required for treatment of patients across Victorian Public Health Services

b. The categories required include:

CATEGORY NUMBER	CATEGORY NAME
1	Hypodermic Needles

CATEGORY NUMBER	CATEGORY NAME
2	Blunt and Filter Needles
3	Hypodermic Syringes
4	Insulin Syringes with Integral Needle
5	Catheter Tip Syringes
6	Insulin Pen Needles
7	Hypodermic Syringe with Integral Needle or Combo pack with Syringe & Needle separated
8	Hypodermic Syringes with Fixed Needle, Colour Differentiated for Needle and Syringe Program (NSP)

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

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

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

4. Product Offering

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

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

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

   (i) HPVC2015-005 Hypodermic Needles and Syringes

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

5. Clinical Trials

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

Product Requirements

6. Standards and Compliance

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

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

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

7. Packaging and Labelling

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

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

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

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.

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.

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 HSV category and subcategory number.

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

f. HSV may not consider unlabelled submissions.

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

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

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

   (ii) Is incomplete as to clause c.

i. Product samples are not to be provided unless specifically requested by HSV, as per Part 2 clause **Error! Reference source not found. Error! Reference source not found.**.

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

10. Warranty

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

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

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

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

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

11. 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 clause 6 Warranty, where applicable.

12. Price review

a. Except where detailed in Item 9 of the Supply Schedule, the Unit Prices must remain fixed for the Term of this Agreement and no further adjustment of the Unit Prices shall take place.

b. If the parties do agree to a change in the Unit Prices of the Goods, such agreement must be in writing.

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. Hypodermic Needles and Syringes will be delivered to the location(s) specified by Participating Health Services within the shortest possible timeframe; however, this must not exceed three (3) Business Days from receipt of order unless otherwise agreed with the Participating Health Service.

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

15. Urgent Deliveries

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

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

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

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) online training modules

   (iii) off-site study days for clinicians

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

   (v) training materials.

17. Customer Service and Support

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

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

   (i) inherently familiar with the contracted products

   (ii) appropriately qualified

   (iii) technically/clinically knowledgeable about the contracted products

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

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; 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.

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 Part 4 clause 11 Recall Process).

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

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

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

Category 1 – Hypodermic Needles

a. A full range of sterile, single use Hypodermic, including for intravitreal injection is required to meet clinical needs.

All needles offered shall include:

(i) Brand name

(ii) non-safety and safety.

(iii) needle gauge e.g. 25G, 33G

(iv) needle length in millimetres e.g. 25mm, 32mm, 38mm, 50mm

(v) needle wall type e.g. thin wall, ultra-thin wall

(vi) needle hub colour e.g. black

(vii) needle bevel type e.g. intradermal

(viii) needle is non-coring

Note: All safety needles shall be capable of single-handed activation.

Category 2 – Blunt and Filter Needles

a. A range of sterile, single use blunt and filter needles for drawing up of medication, is required to meet clinical needs.

b. All needles offered shall include:

(i) Brand name.

(ii) needle gauge e.g., 18G;

(iii) needle length in millimetres e.g., 38mm;

(iv) needle wall type e.g., thin wall

(v) hub colour e.g., red

(vi) where a filter is present

- size of the filter in microns; and
- if the filter is low protein binding.

(vii) needle is non-coring

Category 3 – Hypodermic Syringes

a. A full range of sterile, single use plastic hypodermic syringes including for intravitreal injection is required to meet clinical needs.

All syringes offered shall include:

(i) Brand name

(ii) Safety and non-safety

(iii) a full range of sizes and volumes e.g.,30mL

(iv) connector type: luer lock and luer slip

(v) volume of dead space in millilitres

(vi) option of Low Dead Space syringes – Less than 0.03mL

(vii) with concentric and eccentric tips

(viii) clear barrel with clear or coloured plunger

(ix) coloured barrel (barrel must be transparent so that fluid level can be seen) with clear-or coloured plunger

(x) have bold scale graduations for easy visualisation and accurate dosing that resist removal

(xi) have an integral mechanism within the syringe barrel to prevent easy withdrawal of the plunger rod from the barrel; and

(xii) provide smooth plunger action for ease of administration.

(xiii) provide internal and external diameter of barrel for syringes uses in conjunction with syringe drivers in millimetres

(xiv) Coating of syringe e.g., with or without silicone oil

Note: All safety syringes shall be capable of single-handed activation.

Use and Performance of Hypodermic Syringes in Syringe Pumps

b. Hypodermic syringes shall be compatible with and must not adversely affect the performance of electronic syringe pumps.

c. Hypodermic syringes shall:

(i) be recognisable by brand and volume on loading into a syringe pump
(ii) not affect the performance within specification of syringe pumps nor cause alarm conditions when infusing injectable fluids and drugs including viscous fluids
(iii) not affect the performance of syringe pumps when infusing over the full range of available flow rates and syringe sizes. This is particularly important in low flow rate situations; and
(iv) not adversely affect the performance of the syringe pumps by interrupting or ceasing continuity of flow during infusion, nor by micro bolusing following resumption of flow due to adhesion between the elastomeric stopper and the syringe barrel i.e., syringe ‘stiction’.

Category 4 – Insulin Syringes with Integral Needle

a. A full range of sterile, single use plastic insulin syringes with integral needle is required to meet clinical needs.

b. All syringes offered shall include:

(i) brand name
(ii) safety and non-safety.
(iii) volume of syringe in millilitres and international units e.g. 1mL
(iv) volume of dead space in millilitres
(v) option of Low Dead Space syringes – Less than 0.03mL
(vi) have a clear syringe barrel
(vii) have bold scale graduations for easy visualisation and accurate dosing that resist removal
(viii) have an integral mechanism within the syringe barrel to prevent easy withdrawal of the plunger rod from the barrel; and
(ix) provide smooth plunger action for ease of administration.
(x) type of plastic material used for both barrel and plunger e.g., polyethylene.

c. Since integral needle is incorporated, it shall comply with the specifications as previously described in Category 1 - Hypodermic Needles.

d. All needles offered shall include:

(i) brand name
(ii) safety and non-safety.
(iii) needle gauge e.g., 27G
(iv) needle length in millimetres e.g. 4mm,13mm
(v) needle wall type e.g. thin wall and ultra-thin wall
(vi) volume of dead space in millilitres
(vii) retractable or not

Note: All safety insulin syringes with an integral needle shall be capable of single-handed activation

Category 5 – Catheter Tip Syringes

a. A full range of sterile catheter tip syringes is required to meet clinical needs.

b. All Catheter Tip Syringes offered shall include:

(i) brand name
(ii) single use or single patient use
(iii) volume of syringe in millilitres, e.g., 60mL
(iv) volume of dead space in millilitres
(v) catheter tip configuration e.g., straight or curved
(vi) have a clear syringe barrel
(vii) have bold scale graduations for easy visualisation and accurate dosing that resist removal
(viii) have an integral mechanism within the syringe barrel to prevent easy withdrawal of the plunger rod from the barrel; and
(ix) provide smooth plunger action for ease of administration; and
(x) type of plastic material used for both barrel and plunger e.g. polyethylene.

Category 6 – Insulin Pen Needles

a. A full range of sterile, single use, safety Insulin Pen Needles is required to meet clinical needs.

b. All Pen Needles offered shall include:

(i) brand name
(ii) needle gauge e.g., 30G
(iii) needle length in millimetres, e.g. 4mm, 8mm;
(iv) needle wall type e.g., thin wall.
(v) Insulin pen needles accessories e.g. attachment

Note: all safety needles shall be capable of single-handed activation.

Category 7 – Hypodermic Syringe with Integral Needle or Combo pack with Syringe & Needle separated

a. A full range of sterile, single use plastic hypodermic syringes is required to meet clinical needs.

b. All syringes offered shall include:

(i) Brand name

(ii) non safety and safety

(iii) a full range of syringe sizes and volumes e.g.,3mL;

(iv) luer lock and luer slip

(v) volume of dead space in millilitres

(vi) Option of Low Dead Space syringes – Less than 0.03mL

(vii) with concentric and eccentric tips

(viii) clear barrel with clear or coloured plunger

(ix) coloured barrel (barrel must be transparent so that fluid level can be seen) with clear or coloured plunger

(x) have bold scale graduations for easy visualisation and accurate dosing that resist removal

(xi) have an integral mechanism within the syringe barrel to prevent easy withdrawal of the plunger rod from the barrel

(xii) provide smooth plunger action for ease of administration.

(xiii) type of plastic material used for both barrel and plunger e.g. polyethylene

Note: All safety syringes shall be capable of single-handed activation.

c. Needles (integral or in combo pack) shall comply with the specifications as described in Category 1 - Hypodermic Needles.

d. All needles offered shall include:

(i) Brand name

(ii) non-safety and safety.

(iii) needle gauge e.g., 25G

(iv) needle length in millimetres e.g., 25mm

(v) needle wall type e.g., thin wall, ultra-thin wall

(vi) needle hub colour e.g., black

(vii) needle bevel type e.g., intradermal

(viii) needle is non-coring

(ix) retractable or not

Use and Performance of Hypodermic Syringes in Syringe Pumps

e. Hypodermic syringes shall be compatible with and must not adversely affect the performance of electronic syringe pumps.

f. Hypodermic syringes shall:

(i) be recognisable by brand and volume on loading into a syringe pump

(ii) not affect the performance within specification of syringe pumps nor cause alarm conditions when infusing injectable fluids and drugs including viscous fluids

(iii) not affect the performance of syringe pumps when infusing over the full range of available flow rates and syringe sizes. This is particularly important in low flow rate situations; and

(iv) not adversely affect the performance of the syringe pumps by interrupting or ceasing continuity of flow during infusion, nor by micro bolusing following resumption of flow due to adhesion between the elastomeric stopper and the syringe barrel i.e., syringe 'stiction'.

Category 8 Hypodermic Syringes with Fixed Needle, Colour Differentiated for Needle and Syringe Program (NSP)

a. A full range of sterile, single use plastic hypodermic syringes is required to meet clinical needs.

b. All syringes offered shall include:

(i) Brand name

(ii) Syringe volume of 1mL

(iii) a range of coloured plungers for each needle gauge

(iv) barrel must be clear and transparent (fluid level can be seen)

(v) have bold scale graduations for easy visualisation and accurate dosing that resist removal in millimetres;

(vi) have an integral mechanism within the syringe barrel to prevent easy withdrawal of the plunger rod from the barrel;

(vii) provide smooth plunger action for ease of administration

c. For fixed needle, it shall comply with the specifications as described in Category 1 - Hypodermic Needles.

d. All needles offered shall include:

(i) Brand name

(ii) needle gauge to be both 27G and 29G, if possible

(iii) needle length in millimetres, no greater than 13mm

(iv) needle wall type e.g., thin wall

(v) needle hub colour e.g., white

(vi) a matching range of coloured cap for needles, preference will be given to a matching range

(vii) needle bevel type e.g., intradermal

(viii) needle is non-coring

Appendix 1 - Product List

Category		Subcategory	
1	Hypodermic Needles	1.01	Hypodermic needle, non-safety
		1.02	Hypodermic needle, safety
2	Blunt and Filter Needles	2.01	Blunt needle
		2.02	Filter needle
3	Hypodermic Syringes	3.01	Hypodermic syringe, non-safety, luer slip, concentric
		3.02	Hypodermic syringe, non-safety, luer slip, concentric, coloured barrel or plunger
		3.03	Move to 7.01
		3.04	Hypodermic syringe, non-safety, luer slip, eccentric
		3.05	Hypodermic syringe, non-safety, luer lock, concentric
		3.06	Hypodermic syringe, non-safety, luer lock, concentric, coloured barrel or plunger
		3.07	Hypodermic syringe, safety, luer slip, concentric
		3.08	Move to 7.03
		3.09	Hypodermic syringe, safety, luer lock, concentric
		3.10	Move to 7.04
4	Insulin Syringe with Integral Needle	4.01	Insulin syringe with integral needle, non-safety
		4.02	Insulin syringe with integral needle, safety
5	Catheter Tip Syringes	5.01	Catheter tip syringe, straight tip
		5.02	Catheter tip syringe, curved tip
6	Insulin Pen Needles	6.01	Insulin pen needle, safety
		6.02	Insulin pen needle accessories
7	Hypodermic Syringe with Integral needle or Combo pack with Syringe & Needle separated	7.01	Hypodermic syringe, non-safety, luer slip, concentric, with integral needle (previous 3.03)
		7.02	Hypodermic syringe, non-safety, luer lock, concentric, with integral needle

Category		Subcategory	
		7.03	Hypodermic syringe, safety, luer slip, concentric, with integral needle (previous 3.08)
		7.04	Hypodermic syringe, safety, luer lock, concentric, with integral needle (previous 3.10)
		7.05	Combo pack: Hypodermic syringe, non-safety, luer slip, concentric, with needle separated.
		7.06	Combo pack: Hypodermic syringe, non-safety, luer lock, concentric, with needle separated.
		7.07	Combo pack: Hypodermic syringe, safety, luer slip, concentric, with needle separated.
		7.08	Combo pack: Hypodermic syringe, safety, luer lock, concentric, with needle separated.
8	Hypodermic Syringe with Fixed Needle, Colour Differentiated, for Needle and Syringe Program (NSP)	8.01	Hypodermic syringe with Fixed Needle, Colour Differentiated, 1mL, Whole Range, no greater than 13mmfor Needle and Syringe Program (NSP)

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 Hypodermic Needles and Syringes may include, but is not limited to:

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

STANDARD NUMBER	STANDARD NUMBER
Standard 3– Preventing and Controlling Healthcare Associated Infections	National Safety and Quality Health Service Standards by Australian Commission on Safety and Quality in Health Care (ACSQHC).
ISO 7864 / AS 1946	Sterile hypodermic needles for single use.
ISO 594-1	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 1: General requirements.
ISO 594-2	Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 2: Lock fittings.
ISO 6009	Hypodermic needles for single use -- Colour coding for identification.
ISO 7886-1	Sterile hypodermic syringes for single use -- Part 1: Syringes for manual use.
ISO 7886-2	Sterile hypodermic syringes for single use -- Part 2: Syringes for use with power-driven syringe pumps.
ISO 7886-4	Sterile hypodermic syringes for single use -- Part 4: Syringes with re-use prevention feature.
ISO 8537	Sterile single-use syringes, with or without needle, for insulin.
ISO 9626	Stainless steel needle tubing for the manufacture of medical devices.
ISO 11608-1	Needle-based injection systems for medical use -- Requirements and test methods -- Part 1: Needle-based injection systems.
ISO 11608-2	Needle-based injection systems for medical use -- Requirements and test methods -- Part 2: Needles.

STANDARD NUMBER	STANDARD NUMBER
ISO 11608-3	Needle-based injection systems for medical use -- Requirements and test methods -- Part 3: Finished containers.
ISO 11135	Sterilisation of health care products – Ethylene oxide.
AS/NZS 4187:2019	Cleaning, disinfecting, and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities.
AS1079.4	Packaging of items (sterile) for patient care. Part 4: Flexible Packaging Systems – for single use in hospitals.
EN11137	Sterilisation of health care product – Radiation.

Legislation

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

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

(ii) *Therapeutic Goods Act* 1989

Guidelines and Other References

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

(i) NHMRC (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*