

Human Tissue Act 1982 (Vic) (the Act)

PERMIT UNDER SECTION 39(2)

This permit is issued under Section 39(2) of the Act, by reason of special circumstances to **permit the following specified persons:**

1. **Victorian Public Hospitals and Health Services listed in Schedules 1 (Public Hospitals) 2, (Denominational Hospitals), 5 (Public Health Services) of the *Health Services Act 1988*; and**
2. **Victorian Private Hospitals (including privately operated public hospitals) and day procedure centres registered as Health Service Establishments under part 4 of the *Health Services Act 1988*.**
3. **A Clinical Training Facility listed in Attachment 1**
for the following Permitted Purposes only:
 - *the teaching and study of anatomy and for the carrying on of the practice of anatomy, including research, and the conduct of surgical examinations and surgical training where applicable.*

to buy the following products from ConMed Linvatec Australia Pty Ltd:

Musculoskeletal Tissue - ConMed Linvatec Australia Pty Ltd — (ARTG identifier 299298)

1. **Bone, Segmented, Frozen - L**
2. **Tendon, Freeze dried - L**
3. **Fascia lata, Freeze dried - L**
4. **Bone, Morcellised, Demineralised, Freeze dried — L**
5. **Tendon with Bone, Frozen - L**
6. **Bone, Morsellised, Freeze dried - L**
7. **Tendon, Frozen - L**
8. **Meniscus, Frozen - L**
9. **Tendon with Bone, Freeze dried - L**
10. **Fascia lata, Frozen - L**
11. **Meniscus with Bone, Frozen - L**
12. **Bone segmented, Freeze dried — L**
13. **Cartilage, Morsellised, Freeze dried — L**
14. **Cartilage, Morsellised, Frozen - L and Cartilage, Morsellised, Freeze dried — L**

Skin - ConMed Linvatec Australia Pty Ltd — (ARTG identifier 299299)

1. **Dermis — L — AlloPatchHD**
2. **Dermis, Freeze dried — L – AlloPatchHD**

Products under the Therapeutic Goods Administration Special Access Scheme (SAS) in the following circumstances and/or for the following permitted purposes:

1. **where an orthopaedic surgeon has deemed it necessary for their patient (living patient surgery ONLY) and**
2. **there is no other alternative product listed on the ARTG, in entry 299298 or 299299 (listed above)**

Conditions and restrictions:

This permit is issued subject to the following terms, conditions, limitations or restrictions:

1. The Minister may cancel the permit at any time.
2. ConMed Linvatec Australia Pty Ltd must only sell the products to specified persons and must take all reasonable steps to determine that the purchaser of the product is a specified person; and
3. ConMed Linvatec Australia Pty Ltd must be satisfied that the Clinical Training Facility is an approved School of Anatomy and authorised to conduct the teaching and study of the anatomy.
4. ConMed Linvatec Australia Pty Ltd must provide a copy of the valid permit to the specified persons before the specified persons purchase the products from ConMed Linvatec Australia Pty Ltd unless it has been previously provided by ConMed Linvatec Australia Pty Ltd.
5. Where a product listed above is included on the ARTG, the specified persons can only buy the product for the purposes listed under the relevant ARTG registration.
6. ConMed Linvatec Australia Pty Ltd must comply with any of the standard conditions or product specific conditions specified by the Therapeutic Goods Administration.
7. ConMed Linvatec Australia Pty Ltd must notify *Human Tissue - Health Regulator* of any changes or variations in respect of any information concerning the products that would have been relevant to a decision by the Therapeutic Goods Administration to include the products on the ARTG, that have been notified to the Therapeutic Goods Administration.
8. In order to enable *Human Tissue - Health Regulator* to monitor compliance with this permit and evaluate whether this permit is operating in the public interest, the specified persons and/or ConMed Linvatec Australia Pty Ltd must provide to *Human Tissue - Health Regulator* or a person nominated by *Human Tissue - Health Regulator* any documents or information requested by *Human Tissue - Health Regulator* or their nominee within twenty (20) business days of receiving a request to provide such documents or information. Such a request could include the provision of information about the number and kind of products purchased by specified persons in relation to the period specified by *Human Tissue - Health Regulator*.
9. The specified persons must comply with the terms of this permit at all times and must notify the Human Tissue - Health Regulator as soon as practicable if there is reason to believe that the terms of this permit are not being met.

The permit remains in force for five (5) years from the date of execution, unless cancelled earlier by notice in writing.

Date: 26 06/2024



Hon Mary-Anne Thomas MP
Minister for Health
Minister for Health Infrastructure
Minister for Ambulance Services

Date: 26 06/2024

Definitions

In this permit

- ARTG means the Australian Register of Therapeutic Goods
- TGA means the Therapeutic Goods Administration means the regulatory authority of the Commonwealth Department of Health responsible for the administration of the Therapeutic Goods Act 1989
- A School of Anatomy means a prescribed institution or a place which has been authorised under the Act to operate as a School of Anatomy by the Minister for Health by notice published in the Victoria Government Gazette.
- Year means a period of 12 months

Extract of the *Human Tissue Act 1982*

38 Unauthorized selling of tissue prohibited

- (1) Subject to this section, a person shall not sell, or agree to sell, tissue (including his own tissue) or the right to take tissue from his body.
Penalty: 50 penalty units.
- (2) Nothing in subsection (1) applies to a sale, or an agreement to sell, to a person who is, or is reasonably believed by the vendor to be, acting subject to, and in accordance with, a permit granted under section 39(2).
- (3) Subsection (1) does not apply to the receiving of reasonable expenses of a kind referred to in section 17 of the *Prohibition of Human Cloning for Reproduction Act 2008*.

39 Unauthorized buying of tissue prohibited

- (1) Subject to this section, a person shall not buy, agree to buy, offer to buy, hold himself out as being willing to buy, or inquire whether a person is willing to sell to the person or another person—
 - (a) tissue; or
 - (b) the right to take tissue from the body of another person.Penalty: 100 penalty units or imprisonment for six months, or both.
- (1A) Subsection (1) does not apply to the giving of reasonable expenses of a kind referred to in section 17 of the *Prohibition of Human Cloning for Reproduction Act 2008*.
- (2) Where he considers it desirable by reason of special circumstances so to do, the Minister may, by a permit in writing, authorize a person, subject to such conditions and restrictions as may be specified in the permit, to buy tissue (other than spermatozoa or ova) or the right to take tissue (other than spermatozoa or ova) from the body of another person.
- (3) Nothing in subsection (1) applies to anything done under and in accordance with a permit granted under subsection (2).
- (4) The Minister may at any time, by notice in writing given to a person to whom a permit has been granted under this section, cancel the permit.
- (5) Where a permit has been granted under subsection (2) subject to any conditions or restrictions specified in the permit, a person shall not act on the authority of the permit unless the conditions or restrictions, as the case may be, are or have been complied with.
- (6) A person who contravenes subsection (5) is guilty of an offence and liable to a penalty not exceeding 50 penalty units or imprisonment for three months, or both.

Attachment 1

Clinical Training Facilities for the purpose of permit T-2024-001

The following Clinical Training Facilities have been permitted to buy products from ConMed Linvatec Australia Pty Ltd as listed on permit **T-2024-001** as a specified person for the following Permitted Purposes only:

the teaching and study of anatomy and for the carrying on of the practice of anatomy, including research, and the conduct of surgical examinations and surgical training where applicable.

- 1. The Anatomical and Surgical Skills Laboratory, School of Biomedical Sciences, The University of Melbourne, Parkville VIC 3052**
- 2. Royal Australian College of Surgeons, Skills & Education Centre, 250-290 Spring Street, East Melbourne VIC 3002**

The Clinical Training Facility as listed above must have current authorisation as a School of Anatomy in Victoria.