

Background

- A. Trajan develops and commercialises products for use in analytical and life sciences.
- B. Trajan has developed the Device for blood storage and collection and is making the Device available to third parties who wish to acquire and use the Device for research purposes.
- C. The Device has not been registered as a Medical Device on the ARTG, or within the equivalent regulatory framework of the Receiving Territory, and can only be supplied for limited purposes.
- D. Trajan wishes to supply, and the Purchaser wishes to purchase, the Devices solely for use for the Authorised Purpose.
- E. Any Order for Devices placed by Purchaser and accepted by Trajan will be governed by these Terms and Conditions.

1. Definitions and Interpretation

- 1.1 In this document, the following definitions apply unless the context requires otherwise:

ARTG means Australian Register of Therapeutic Goods;

Authorised Purpose means use of the Devices for non-therapeutic and non-diagnostic purposes for research use only;

Business Day means a day which is Monday to Friday (inclusive) and which is not a public holiday in the State of Victoria, Australia;

Confidential Information means any information disclosed by either Trajan or Purchaser (as the “**Disclosing Party**”) to the other party (as the “**Receiving Party**”) which is designated as confidential or which by its nature is confidential or which is disclosed in circumstances importing an obligation of confidence, but does not include information which:

- (a) is or becomes available to the Receiving Party or to the public other than as a result of a breach of any duty of confidentiality owed to the Disclosing Party;
- (b) has been independently developed by Receiving Party without accessing the Confidential Information of the Disclosing Party; or
- (c) is required to be disclosed by law;

Device means the blood collection and storage device known as “hemaPEN®”;

Disclosing Party has the meaning given to that term in the definition of Confidential Information;

Excluded Purposes means any use of the Devices which is not for the Authorised Purpose, and includes (but is not limited to) the Devices being used in or in connection with:

- (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or
- (b) influencing, inhibiting or modifying a physiological process in persons; or
- (c) testing the susceptibility of persons to a disease or ailment; or
- (d) influencing, controlling or preventing conception in persons; or
- (e) testing for pregnancy in persons; or
- (f) the replacement or modification of parts of the anatomy in persons;

Instructions For Use means the instructions for use of the Devices (whether set out in a document, video presentation or in any other form) provided by Trajan to Purchaser, as amended or modified from time to time by written notice to Purchaser;

Intellectual Property means any registered or unregistered intellectual property rights including patents, trade marks and service marks, designs, copyrights, database rights, design rights, Confidential Information, know-how, trade secrets, applications for any of the above, and any similar right recognised in any jurisdiction, together with all rights of action in relation to the infringement of any of the above;

Medical Device has the meaning given in the Therapeutic Goods Act and under equivalent laws in the Receiving Territory;

Modifications means any modification, alteration or improvement to a Device;

Order means an order placed by Purchaser for the supply of Devices;

Personal Information has the meaning given in the *Privacy Act 1988* (Cth) and under equivalent laws in the Receiving Territory;

Price means the price payable by Purchaser for the Devices;

Publish means to publicly communicate in any form and through any means, including in any hard copy, electronic, online or oral communication and **Publication** has the corresponding meaning;

Purchaser means the person or entity who placed the Order for the supply of the Devices and any successor in title to those Devices;

Recall Request means a request by Trajan to Purchaser to return all unused Devices to Trajan;

Receiving Party has the meaning given to that term in the definition of Confidential Information;

Receiving Party Authorised Persons has the meaning given to that term in clause 5.1;

Receiving Territory means the country or region in which the Purchaser will receive the Devices from Trajan, together with any other country or region in which the Purchaser will use the Devices received from Trajan;

Terms and Conditions means these terms and conditions for supply of the Devices to Purchaser;

TGA means the Therapeutic Goods Administration;

Therapeutic Goods Act means the *Therapeutic Goods Act 1989* (Cth); and

Trajan means Trajan Scientific Australia Pty Ltd ACN 161 314 969 together with its officers, employees and agents.

- 1.2 The following rules of interpretation apply unless the context requires otherwise:

- (a) headings are for convenience only and do not affect interpretation;
- (b) the singular includes the plural and conversely;
- (c) where a word or phrase is defined, its other grammatical forms have a corresponding meaning;
- (d) a reference to a clause is to a clause of these Terms and Conditions;
- (e) a reference to conduct includes, without limitation, any omission, statement or undertaking, whether or not in writing;
- (f) a reference to any statute, law or regulation shall be construed as a reference to that statute, law or regulation as amended at the relevant time.

2. Confirmation of Order and binding agreement

- 2.1 An Order placed by a Purchaser will not be binding on Trajan unless and until Trajan accepts the Order. Trajan may accept an Order by taking any steps to confirm or satisfy the Order.
- 2.2 Upon acceptance of an Order, Purchaser and Trajan enter into a binding agreement for the supply of the Devices on these Terms and Conditions.

3. Supply of the Devices

- 3.1 In return for the payment of the Price in the manner directed by Trajan, Trajan agrees to supply the Devices to Purchaser.

4. Use of the Devices

- 4.1 Purchaser acknowledges that the Device:
 - (a) is not listed on the ARTG or within the equivalent regulatory framework of the Receiving Territory;
 - (b) has not been approved by the TGA or any equivalent regulatory body in the Receiving Territory;
 - (c) does not have regulatory approval for, and is not being supplied for, use by Purchaser for any Excluded Purposes; and
 - (d) is not intended to be supplied to the Purchaser for any purpose other than for the Authorised Purpose.
- 4.2 Purchaser will use the Devices solely for the Authorised Purpose and for no other purpose (whether commercial or non-commercial), unless it obtains the prior written consent of Trajan.
- 4.3 Purchaser will not use the Devices for an Excluded Purpose.
- 4.4 Purchaser will use the Devices in accordance with the Instructions for Use.
- 4.5 Purchaser will not modify or attempt to reverse engineer, deconstruct or in any way determine the structure or operation of the Device.
- 4.6 Purchaser will comply with all legislation, regulations, codes and guidelines applicable to its importation, handling and use of the Devices (including complying with legal requirements relating to the labelling of the Devices, and the handling and use of Personal Information obtained or generated by Purchaser) which are effective in the Receiving Territory.
- 4.7 Purchaser will not remove, modify or make any additions to the labels on the Devices without the prior written consent of Trajan.
- 4.8 Purchaser is responsible for Purchaser’s safe handling, storage, use and disposal of the Devices, to ensure that the Devices will not cause any loss or harm to any person.
- 4.9 Purchaser acknowledges and agrees that it is:
 - (a) aware of all matters that concern the safe handling, storage, use and disposal of the Devices; and
 - (b) has the facilities, skills and expertise that are required for the safe handling, storage, use and disposal of the Devices.
- 4.10 Once Purchaser has used a Device, Purchaser will promptly dispose of the Device following appropriate biohazard precautions and processes.

- 4.11 Trajan may, in its sole discretion, issue a Recall Request for any Devices which have been supplied under these Terms and Conditions. Upon receiving a Recall Request, Purchaser must immediately cease use of the Devices, and return all unused Devices to Trajan within ten (10) Business Days or such other period as may be agreed in writing with Trajan. Where Trajan has issued a Recall Request, Trajan will refund the Purchaser the portion of the Price paid for the unused Devices.
- 4.12 Purchaser agrees to provide Trajan with accurate and comprehensive information regarding how the Purchaser used the Devices, as may be reasonably requested by Trajan in order to respond to any requests for information from any regulatory authority or for Trajan to otherwise be satisfied that the Purchaser has used the Devices strictly in accordance with these Terms and Conditions. Trajan will comply with clause 5 below in relation to any of the Purchaser's Confidential Information provided to Trajan under this clause.
- 4.13 Purchaser must not market, offer for sale, sell, supply or otherwise make available the Device to any third party unless it obtains the prior written consent of Trajan.
- 5. Confidentiality**
- 5.1 In relation to all Confidential Information disclosed by the Disclosing Party in connection with the supply and use of the Devices, the Receiving Party agrees:
- to maintain confidentiality in the Confidential Information;
 - to protect the Confidential Information using the same degree of care as the Receiving Party uses to protect its own Confidential Information, but in any event no less than a reasonable degree of care;
 - to restrict access to the Confidential Information to employees and officers of the Receiving Party ("**Receiving Party Authorised Persons**") who:
 - reasonably require access to the Confidential Information for a purpose in connection with the supply and use of the Devices;
 - are aware that the Confidential Information must be kept confidential;
 - agree to use the Confidential Information only in accordance with these Terms and Conditions (it being the case that Receiving Party must ensure that each Receiving Party Authorised Person observes all of the obligations imposed on Purchaser under these Terms and Conditions); and
 - not to distribute or disclose the Confidential Information to any third parties other than with Disclosing Party's prior written consent.
- 5.2 At any time upon receipt of a written request from Disclosing Party, Receiving Party will (as directed) return to Disclosing Party, or destroy, any and all copies of the Confidential Information, except for one copy which may be retained by Receiving Party for record keeping purposes.
- 5.3 The confidentiality obligations imposed on the Receiving Party in these Terms and Conditions shall continue to apply unless otherwise agreed in writing with the Disclosing Party.
- 6. Publications**
- 6.1 Purchaser may refer to its use of the Devices in any Publication provided that any reference to the name of the Device is strictly in the form "hemaPEN[®]".
- 7. Intellectual Property**
- 7.1 Purchaser agrees that the sale of the Devices under these Terms and Conditions does not convey to Purchaser any rights or interests whatsoever to the Device, Modifications, Confidential Information or the associated Intellectual Property (which are owned by and vest in Trajan on their creation), other than the right to use the Device for the Authorised Purpose.
- 7.2 Purchaser must not lodge any patent application or other application for the statutory protection of the Device, Modifications or any Confidential Information.
- 7.3 Purchaser agrees that all of the obligations set out in these Terms and Conditions in relation to the Devices shall apply equally in relation to any Modifications.
- 7.4 Purchaser must immediately notify Trajan of any suspected or actual unauthorised access, use, reproduction or disclosure of the Devices or any Trajan Confidential Information.
- 8. Liability and indemnities**
- 8.1 To the extent permitted by applicable law:
- Purchaser acknowledges that it bears the sole risk and assumes all responsibility and liability in connection with its handling and use of the Devices and Confidential Information under these Terms and Conditions;
- Trajan excludes all warranties, express or implied, including any warranty as to fitness for a particular purpose, any warranty as to sterility or safety of the Devices, and any warranty against infringement of Intellectual Property rights;
- Trajan's total liability to Purchaser for any loss or damage of any kind, however caused, due to Trajan's negligence, breach of contract, breach of any law, in equity, or otherwise, arising out of all acts, omissions and events in connection with the supply of the Devices is limited to the following, at the sole discretion of Trajan:
 - the replacement of the Devices; or
 - payment of the amount equivalent to the Price paid by Purchaser for the Devices supplied;
- Trajan excludes all liability, for consequential or incidental damages, third party claims or loss of profits, revenue, goodwill or opportunities in contract, tort, under any statute or otherwise (including negligence); and
- Purchaser hereby indemnifies Trajan against all liability, loss, costs, damages or expenses (including legal costs and expenses) incurred or suffered as a result of:
 - the use by Purchaser or any third party authorised by Purchaser, of the Devices or Trajan's Confidential Information; or
 - any breach by Purchaser of these Terms and Conditions.
- 9. Insurance**
- 9.1 Purchaser warrants that it has in place and will maintain valid and enforceable insurance policies which fully and adequately insure it against any potential liability exposure for it under these Terms and Conditions.
- 9.2 Purchaser acknowledges and agrees that it is Purchaser's responsibility to assess and consider the risks and scope of insurances required under these Terms and Conditions. If requested by Trajan, Purchaser must provide evidence of such current and valid insurance.
- 10. General**
- 10.1 These Terms and Conditions are governed by the laws of the State of Victoria, Australia and the parties irrevocably and unconditionally submit to the exclusive jurisdiction of the Courts of Victoria, Australia.
- 10.2 These Terms and Conditions constitute the entire understanding between the Parties with respect to its subject matter and supersedes all previous written or oral negotiations, commitments and understandings.
- 10.3 If any provision of these Terms and Conditions is void, voidable, unenforceable or illegal in any jurisdiction will not apply in that jurisdiction, but will apply in jurisdictions where it would not be void, voidable, unenforceable or illegal and the rest of these Terms and Conditions will still apply.
- 10.4 Any provisions contained in these Terms and Conditions which are expressed to or are, by their nature, intended to survive expiry or termination of any agreement entered into under clause 2.2 will survive expiry or termination of that agreement.
- 10.5 These Terms and Conditions may only be varied or amended by signed, written agreement.
- 10.6 Neither party may assign, transfer, charge, encumber or otherwise deal with any of its rights or obligations under these Terms and Conditions or under any agreement entered into under clause 2.2, or attempt or purport to do so, without the prior written consent of the other party.
- 10.7 A failure to exercise or a delay in exercising any right, power or remedy under these Terms and Conditions, or under any agreement entered into under clause 2.2, does not operate as a waiver. A single or partial exercise or waiver of the exercise of any right, power or remedy does not preclude any other or further exercise of that, or any other right, power or remedy. A waiver is not valid or binding on the party granting that waiver unless made in writing.