

Background

- A. Trajan develops and commercializes products for use in analytical and life sciences, including the hemaPEN (“Device”).
- B. Trajan has developed the Device and is making the Device available to third parties who wish to acquire the Device for use by Health Professionals.
- C. The Device has been CE-marked in accordance with Directive 98/79/EC (as amended) (“IVD Directive”) and shall only be supplied for the Authorized Purpose.
- D. Trajan wishes to supply, and the Purchaser wishes to purchase, the Devices solely for use for the Authorized 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:
- 1.2 **Authorized Purpose** means intended purpose of the Device as described in article 1(2)(h) of the IVD Directive, and concerns the use for which the Device is intended according to the information provided by the manufacturer on the labelling, the Instructions For Use or in promotional materials for the device;
Business Day means a day which is Monday to Friday (inclusive), and which is not a public holiday in England;
- 1.3 **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 or under a valid court order or administrative order;**Device** means the *in-vitro* blood collection and storage device known as “hemaPEN®”;
Disclosing Party has the meaning given to that term in the definition of Confidential Information;
Health Professional has the meaning given in Article 3(f) of Directive 2011/24/EU;
Instructions For Use means the instructions for use of the Devices (whether set out in a document, video presentation, product labelling 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, trademarks 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 recognized in any jurisdiction, together with all rights of action in relation to the infringement of any of the above;
Manufacturer refers to Trajan Scientific Australia Pty Ltd;
Medical Device has the meaning given in the IVD Directive (as amended) and subsequent implementation thereof in the national laws of the Receiving Territory;
Modifications means any modification, alteration or improvement to a Device;
Order means an order placed by Purchaser with Trajan for the supply of Devices;
Personal Data has the meaning given in the General Data Protection Regulation (Regulation 2016/679/EU, “GDPR”) under national data protection law in the Receiving Territory;
Price means the price payable by Purchaser for the Devices, as notified by Trajan from time to time;
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 Authorized Persons has the meaning given to that term in clause 6.1;

Receiving Territory means the country or region in which the Purchaser will receive the Devices from Trajan, or another country or region specified by Trajan in writing. The Receiving Territory shall only include countries that are part of the European Economic Area and the United Kingdom;

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

Trajan means Trajan Scientific Europe Ltd together with its officers, employees and agents.

- 1.4 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. Payment and Supply
- 3.1 Following acceptance of an Order, Trajan will issue Purchaser with an invoice for the Price.
 - 3.2 Purchaser shall pay the invoice within 14 days of the date of the invoice (or within such other period as may be agreed between the parties) and in the manner directed by Trajan in the invoice.
 - 3.3 After receipt of payment of the invoice in the manner directed by Trajan, Trajan shall supply the Devices to Purchaser. Unless otherwise agreed between the parties Trajan shall arrange for the shipping of the Devices, and shipping costs shall be included in the Price.
 - 3.4 Risk of loss in or damage to the Devices passes to Purchaser on the moment the shipment of the Order to Purchaser leaves Trajan’s premises.

4. Use of the Devices

- 4.1 Purchaser acknowledges that the Device:
 - (a) has been CE-marked and is also furthermore compliant with EU IVD Directive 98/79/EC for the Authorized Purpose, for use by Health Professionals in the Receiving Territory; and
 - (b) is not intended to be supplied to the Purchaser for any purposes other than for the Authorized Purpose.
- 4.2 Purchaser warrants that:
 - (a) it will use the Devices solely for the Authorized Purpose and for no other purpose (whether commercial or non-commercial);
 - (b) it will not market, offer for sale, (re-)sell, supply or otherwise make available the Device to third parties without the explicit prior written consent of Trajan;
 - (c) only Health Professionals will use the Devices supplied to Purchaser; and
 - (d) the Devices will only be used in the Receiving Territory.
- 4.3 Purchaser will use the Devices strictly in accordance with the Instructions for Use.
- 4.4 Purchaser will not modify or attempt to reverse engineer, deconstruct or in any way determine the structure or operation of the Device.
- 4.5 Purchaser will comply with all legislation, regulations, codes and guidelines applicable to the handling and use of the Devices (including complying with legal requirements relating to the handling and use of Personal Data obtained or generated by Purchaser). Purchaser shall not provide any Personal Data as described in the GDPR to Trajan, unless such information is necessary for Trajan to adequately handle a device incident and in such instance, only where a suitable legal basis applies to the processing. Where relevant, the Purchaser and Trajan shall discuss the applicable approach.
- 4.6 Purchaser will not remove, modify or make any additions to the labels on the Devices without the prior written consent of Trajan.

- 4.7 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.
- 4.8 Purchaser warrants that it:
- (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.
- 4.9 Once Purchaser has used a Device, Purchaser will promptly dispose of the Device following appropriate biohazard precautions and processes.
- 5. Reporting and recall**
- 5.1 Purchaser must:
- (a) maintain accurate and comprehensive records in relation to:
 - i) any identified malfunction, deterioration or inadequacy in the characteristics or performance of the Device;
 - ii) any identified inadequacy in the design or manufacture, labelling, instructions for use or advertising materials of the Device;
 - iii) any significant unexpected public health concern that may create risks related to use of the Device; or
 - iv) any use of the Device contrary to the use intended by Trajan, including use contrary to the Authorized Purpose or use by a person who is not a Health Professional; and
 - (b) notify Trajan in writing and provide copies of such records listed in clause 5.1(a) as soon as practicable after identification.
- 5.2 Purchaser must immediately notify Trajan of any event involving the Device that:
- (a) represents a serious threat to public health;
 - (b) led to or might lead to death or injury; or
 - (c) might lead to death or injury if it were to occur again;
- and immediately provide Trajan with all information requested in relation to such event. Where possible, the Purchaser shall also provide the defective Device for review by Trajan, the Manufacturer of the Device or the Manufacturer's authorized representative. Purchaser shall also without delay inform Trajan of any complaints pertaining to the Device, notwithstanding whether such complaint has been made by a patient or by a Health Professional.
- 5.3 For each purchased Device, Purchaser shall maintain and provide to Trajan, as may be reasonably requested by Trajan, accurate and comprehensive records of how the Purchaser used the Device, end-user details and traceability information for all Device serial numbers (from the moment legally possible, including the Device's UDI) and available after-sales data (including, but not limited to, Device performance and end-user satisfaction feedback or complaints). Purchaser must also provide, as reasonably requested by Trajan, any information related to Trajan's compliance with government regulations, approvals and statutory authorities.
- 5.4 Trajan may, in its sole discretion, issue a Recall Request for any Devices which have been supplied under these Terms and Conditions. Where Trajan has issued a Recall Request, Trajan will refund the Purchaser the portion of the Price paid for the unused Devices. Upon receiving a Recall Request, Purchaser must:
- (a) immediately cease use of the Devices and return all unused Devices to Trajan within five (5) Business Days or such other period as may be agreed in writing with Trajan. The cost of shipping in case of a recall shall be paid by Trajan; and
 - (b) provide assistance to Trajan in the conduct of any Device recall, market withdrawal, mandatory notification or correction.
- 5.5 Purchaser must maintain the records referred to in clauses 5.1 and 5.3 for a minimum period of seven (7) years after the relevant Device was purchased, in order for Trajan 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.
- 5.6 If requested, Purchaser must allow an auditor or other nominated representative of Trajan to have reasonable access to, and to obtain information from, the Purchaser's records and staff for the purposes of confirming accuracy of reports provided to Trajan under clauses 5.1 and 5.3.
- 6. Confidentiality**
- 6.1 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:
- (a) to maintain confidentiality of the Confidential Information;
 - (b) 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;
- (c) to restrict access to the Confidential Information to employees and officers of the Receiving Party (“**Receiving Party Authorized Persons**”) who:
 - i) reasonably require access to the Confidential Information for a purpose in connection with the supply and use of the Devices;
 - ii) are aware that the Confidential Information must be kept confidential;
 - iii) 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 Authorized Person observes all of the obligations imposed on Purchaser under these Terms and Conditions); and
 - iv) are subject to a written confidentiality obligation;
 - (d) not to distribute or disclose the Confidential Information to any third parties other than with Disclosing Party's prior written consent.
- 6.2 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.
- 6.3 Where the Receiving Party is obliged to disclose Confidential Information due to a legal obligation, a valid court order or an administrative order, the Receiving Party shall enable the Disclosing Party to lodge an objection or to file for an objection against the legal obligation, court order or administrative order.
- 6.4 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. After termination or dissolution of this agreement, the confidentiality obligations shall remain in force for a period of ten (10) years.
- 7. Publications**
- 7.1 Subject to clause 7.2, 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®”. Purchaser shall provide a copy of all intended publications at least thirty (30) days prior to publication for review by Trajan and shall not refer to the hemaPEN if Trajan reasonably objects to such reference.
- 7.2 Unless Trajan has provided prior written consent, Purchaser must not make any statement in any Publication about the capabilities or potential uses of the Device, which is materially different from, or inconsistent with, any statement on Trajan's website.
- 8. Intellectual Property**
- 8.1 Purchaser agrees that the sale of the Devices under these Terms and Conditions does not convey to Purchaser any rights or interests whatsoever in 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 Authorized Purpose.
- 8.2 Purchaser shall not lodge any patent application or other application for the statutory protection of the Device, Modifications or any Confidential Information. Purchaser agrees that Trajan or, where Trajan informs the Purchaser accordingly, the Manufacturer of the Device, shall own all intellectual property rights in relation to any developments of the Device and any modifications thereto. Purchaser shall assist Trajan and/or the Manufacturer accordingly in the vesting of any intellectual property rights at Trajan's expense.
- 8.3 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.
- 8.4 Purchaser must immediately notify Trajan of any suspected or actual unauthorized access, use, reproduction or disclosure of the Devices or any Trajan Confidential Information.
- 9. Liability and indemnities**
- 9.1 To the extent permitted by applicable law:
- (a) Purchaser indemnifies and holds harmless Trajan from any claims and damages caused by its handling and use of the Devices and Confidential Information under these Terms and Conditions;
 - (b) 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:

- i) the replacement of the Devices; or
 - ii) payment of the amount equivalent to the Price paid by Purchaser for the Devices supplied;
- (c) 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
- (d) Purchaser hereby indemnifies Trajan against all liability, loss, costs, damages or expenses (including legal costs and expenses) incurred or suffered as a result of:
 - i) the use by Purchaser or any third party authorized by Purchaser of the Devices or Trajan's Confidential Information; or
 - ii) any breach by Purchaser of these Terms and Conditions.

10. Insurance

- 10.1 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.
- 10.2 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.

11. General

- 11.1 These Terms and Conditions are governed by the laws of England and Wales and the parties irrevocably and unconditionally submit to the exclusive jurisdiction of the Courts of England and Wales.
- 11.2 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. Notwithstanding the foregoing, these Terms and Conditions shall be subject to the agreement between Trajan and Purchaser as described in clause 2.2.
- 11.3 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.
- 11.4 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.
- 11.5 These Terms and Conditions may only be varied or amended by written agreement signed by both parties.
- 11.6 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.
- 11.7 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.

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