

Terms and Conditions of Purchase 4th February 2022

1. **Interpretation**
The following definitions and rules of interpretation apply in these Conditions.
- 1.1 **Definitions:**
 - Adverse Incident:** an event involving a medical device, which has produced or has the potential to produce unexpected or unwanted effects involving the safety of patients, users or other persons or has or could result in a product recall for any other reason.
 - Applicable Laws:** all laws applicable to the manufacture and supply of the Deliverables, including, in respect of Deliverables to be used within the medical sector, the Device Regulations, including any laws specifically notified to the Supplier as being applicable to the supply of the Deliverables.
 - Business Day:** a day other than a Saturday, Sunday or public holiday in England, when banks in London are open for business.
 - Commencement Date:** has the meaning given in clause 2.2.
 - Competent Authority:** any federal, state, local, supranational or international regulatory agency, department, bureau, or other governmental entity which is responsible for issuing approvals, licences, registrations, clearances or authorisations necessary for the manufacture, use, storage, import, transport, offering for sale or sale of the Deliverables and/or medical devices in a regulated jurisdiction, including the FDA, EMA and MHRA and any nominee of any of those authorities, and any entity that has been designated by any of those authorities to assess whether a product to be placed on the market meets the requirements of the Device Regulations.
 - Conditions:** these terms and conditions as amended from time to time in accordance with clause 18.8.
 - Contract:** the contract between Kimal and the Supplier for the supply of Goods and/or Services in accordance with these Conditions.
 - Deliverables:** all documents, products and materials developed by the Supplier or its agents, contractors and employees as part of or in relation to the Services in any form or media, including drawings, maps, plans, diagrams, designs, pictures, computer programs, data, specifications and reports (including drafts).
 - Device Regulations:** all applicable laws and regulations applying to the development, manufacture, marketing and supply of medical devices, including the UK Medical Device Regulations 2002, the EU Medical Device Regulation 2017/745 and any applicable industry codes and standards including EN ISO 13485 / EN ISO 9001.
 - EMA:** the European Medicines Agency, or any successor to the EMA.
 - FDA:** the Food and Drug Administration of the United States Department of Health and Human Services, or any successor to any of the previous.
 - Goods:** the goods (or any part of them) set out in the Order.
 - Goods Specification:** any specification for the Goods, including any related plans and drawings, that is agreed in writing by Kimal and the Supplier.
 - Intellectual Property Rights:** patents, utility models, rights to inventions, copyright and neighbouring and related rights, moral rights, trade marks and service marks, business names and domain names, rights in get-up and trade dress, goodwill and the right to sue for passing off or unfair competition, rights in designs, rights in computer software, database rights, rights to use, and protect the confidentiality of, confidential information (including know-how and trade secrets), and all other intellectual property rights, in each case whether registered or unregistered and including all applications and rights to apply for and be granted, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world.
 - Mandatory Policies:** Kimal's business policies listed in the Schedule.
 - MHRA:** the UK Medicines and Healthcare products Regulatory Agency, or any successor to the MHRA.
 - Order:** Kimal's order for the supply of Goods and/or Services, as set out in Kimal's purchase order form.
 - Services:** the services, including any Deliverables, to be provided by the Supplier under the Contract as set out in the Service Specification.
 - Service Specification:** the description or specification for Services agreed in writing by Kimal and the Supplier.
 - Supplier:** the person or firm from whom Kimal purchases the Goods and/or Services.
2. **Basis of contract**
- 2.1 The Order constitutes an offer by Kimal to purchase Goods and/or Services from the Supplier in accordance with these Conditions.
- 2.2 The Order shall be deemed to be accepted on the earlier of:
 - (a) the Supplier issuing written acceptance of the Order; or
 - (b) any act by the Supplier consistent with fulfilling the Order, at which point and on which date the Contract shall come into existence, effective on the date on the Order (**Commencement Date**).
- 2.3 These Conditions apply to the Contract to the exclusion of any other terms that the Supplier seeks to impose or incorporate, or which are implied by law, trade custom, practice or course of dealing.
- 2.4 All of these Conditions shall apply to the supply of both Goods and Services except where the application to one or the other is specified.
- 2.5 The Supplier waives any right it might otherwise have to rely on any term endorsed upon, delivered with or contained in any documents of the Supplier that is inconsistent with these Conditions.
- 2.6 In the event of any conflict between any terms in the Order and these Conditions, the terms in the Order shall prevail.
3. **Supply of Goods**
 - The Supplier shall ensure that the Goods shall:
 - (a) correspond with their description and any applicable Goods Specification;
 - (b) be of satisfactory quality (within the meaning of the Sale of Goods Act 1979) and fit for any purpose held out by the Supplier or made known to the Supplier by Kimal, expressly or by implication, and in this respect Kimal relies on the Supplier's skill and judgement;
 - (c) comply with all Applicable Laws; and
 - (d) where they are manufactured products, be free from defects in design, materials and workmanship and remain so for 12 months after delivery.
 - The Supplier shall ensure that at all times it has and maintains all the licences, permissions, authorisations, consents and permits that it needs to carry out its obligations under the Contract in respect of the Goods.
 - Kimal may inspect and test the Goods at any time before delivery. The Supplier shall remain fully responsible for the Goods despite any such inspection or testing and any such inspection or testing shall not reduce or otherwise affect the Supplier's obligations under the Contract.
 - If following such inspection or testing Kimal considers that the Goods do not comply or are unlikely to comply with the Supplier's undertakings at clause 3.1, Kimal shall inform the Supplier and the Supplier shall immediately take such remedial action as is necessary to ensure compliance.
 - Kimal may conduct further inspections and tests after the Supplier has carried out its remedial actions.
 - Delivery of Goods**
 - The Supplier shall ensure that:
 - (a) the Goods are properly packed and secured in such manner as to enable them to reach their destination in good condition;
 - (b) each delivery of the Goods is accompanied by a delivery note which shows the date of the Order, the Order number (if any), the type and quantity of the Goods (including the code number of the Goods (where applicable)), special storage instructions (if any) and, if the Goods are being delivered by instalments, the outstanding balance of Goods remaining to be delivered; and
 - (c) it states clearly on the delivery note any requirement for Kimal to return any packaging material for the Goods to the Supplier. Any such packaging material shall only be returned to the Supplier at the cost of the Supplier.
 - The Supplier shall deliver the Goods:
 - (a) on the date specified in the Order or, if no such date is specified, then within 14 days of the date of the Order;
 - (b) to the location as is set out in the Order or as instructed by Kimal before delivery (**Delivery Location**); and
 - (c) during Kimal's normal hours of business on a Business Day, or as instructed by Kimal.
 - Delivery of the Goods shall be completed on the completion of unloading of the Goods at the Delivery Location.
 - The Supplier shall not deliver the Goods in instalments without Kimal's prior written consent. Where it is agreed that the Goods are delivered by instalments, they may be invoiced and paid for separately. However, failure by the Supplier to deliver any one instalment on time or at all or any defect in an instalment shall entitle Kimal to the remedies set out in clause 7.1.
 - Title and risk in the Goods shall pass to Kimal on completion of delivery.
 - Supply of Services**
 - The Supplier shall from the date set out in the Order and for the duration of the Contract supply the Services to Kimal in accordance with the terms of the Contract.
 - The Supplier shall meet any performance dates for the Services specified in the Order or that Kimal notifies to the Supplier.
 - In providing the Services, the Supplier shall:
 - (a) co-operate with Kimal in all matters relating to the Services, and comply with all instructions of Kimal;
 - (b) perform the Services with the best care, skill and diligence in accordance with best practice in the Supplier's industry, profession or trade;
 - (c) use personnel who are suitably skilled and experienced to perform tasks assigned to them, and in sufficient number to ensure that the Supplier's obligations are fulfilled in accordance with the Contract;
 - (d) ensure that the Services will conform with all descriptions, standards and specifications set out in the Service Specification, and that the Deliverables shall be fit for any purpose that Kimal expressly or impliedly makes known to the Supplier;
 - (e) provide all equipment, tools and vehicles and such other items as are required to provide the Services;
 - (f) use the best quality goods, materials, standards and techniques, and ensure that the Deliverables, and all goods and materials supplied and used in the Services or transferred to Kimal, will be free from defects in workmanship, installation and design;
 6. **Recalls and Returns**
 - In the event of any potential regulatory exposure such as a recall or Adverse Incident, the Supplier will:
 - (a) as soon as possible and in any event within 48 hours of request, provide to Kimal, copies of all technical documentation, manufacturing records and other documentation relating to the Deliverables which Kimal reasonably requires; and
 - (b) in the event of a return, the Supplier shall provide Kimal with such assistance as Kimal may reasonably request to handle such returns and, at Kimal's request, the Supplier shall use its commercially reasonable efforts to replace the returned Deliverables with new Deliverables within 1 month from the date that Kimal notifies the Supplier about the returned Deliverables.
 - in the event that a product recall or other corrective action, if any, is required in relation to Deliverables supplied to Kimal by the Supplier:
 - (a) Kimal shall control all contacts with the relevant Competent Authority and shall be responsible for coordinating all of the necessary activities in connection with any product recall or other corrective action where the recall or corrective action relates to any item which incorporates any Deliverables provided by the Supplier under this Contract. Kimal shall have ultimate discretion over the contents of any public announcement or disclosure related to the product recall or corrective action. Such release or public statement may contain the Supplier name and/or manufacturing facility; and
 - (b) in all other cases, Kimal shall, at the Supplier's cost, provide such assistance as the Supplier may reasonably require for the purposes of recalling or carrying out such other corrective action (as applicable) in relation to such quantities of Deliverables as may be required whether such Deliverables have been supplied to retail or wholesale customers of Kimal.
 - 6.2 **Kimal remedies**
 - If the Supplier fails to deliver the Goods by the applicable date or to perform the Services by the applicable date, or both, Kimal shall, without limiting or affecting other rights or remedies available to it, have any one or more of the following rights and remedies:
 - (a) to terminate the Contract with immediate effect by giving written notice to the Supplier;
 - (b) to refuse to accept any subsequent performance of the Services and/or delivery of the Goods which the Supplier attempts to make;
 - (c) to recover from the Supplier any costs incurred by Kimal in obtaining substitute goods and/or services from a third party;
 - (d) to require a refund from the Supplier of sums paid in advance for Services that the Supplier has not provided and/or Goods that it has not delivered; and
 - (e) to claim damages for any additional costs, loss or expenses incurred by Kimal which are in any way attributable to the Supplier's failure to meet such dates.
 - If the Supplier has delivered Goods that do not comply with the undertakings set out in clause 3.1, then, without limiting or affecting other rights or remedies available to it, Kimal shall have one or more of the following rights and remedies, whether or not it has accepted the Goods:
 - (a) to terminate the Contract with immediate effect by giving written notice to the Supplier;
 - (b) to reject the Goods (in whole or in part) whether or not title has passed and to return them to the Supplier at the Supplier's own risk and expense;
 - (c) to require the Supplier to repair or replace the rejected Goods, or to provide a full refund of the price of the rejected Goods (if paid);
 - (d) to refuse to accept any subsequent delivery of the Goods which the Supplier attempts to make;
 - (e) to recover from the Supplier any expenditure incurred by Kimal in obtaining substitute goods from a third party; and
 - (f) to claim damages for any additional costs, loss or expenses incurred by Kimal arising from the Supplier's failure to supply Goods in accordance with clause 3.1.
 - If the Supplier has supplied Services that do not comply with the requirements of clause 5.3(d) then, without limiting or affecting other rights or remedies available to it, Kimal shall have one or more of the following rights and remedies:
 - (a) to terminate the Contract with immediate effect by giving written notice to the Supplier;

- (b) to return the Deliverables to the Supplier at the Supplier's own risk and expense;
- (c) to require the Supplier to provide repeat performance of the Services, or to provide a full refund of the price paid for the Services (if paid);
- (d) to refuse to accept any subsequent performance of the Services which the Supplier attempts to make;
- (e) to recover from the Supplier any expenditure incurred by Kimal in obtaining substitute services or deliverables from a third party; and
- (f) to claim damages for any additional costs, loss or expenses incurred by Kimal arising from the Supplier's failure to comply with clause **5.3(d)**.

7.4 These Conditions shall extend to any substituted or remedial services and/or repaired or replacement goods supplied by the Supplier.

7.5 Kimal's rights and remedies under the Contract are in addition to, and not exclusive of, any rights and remedies implied by statute and common law.

8. Kimal's obligations

8.1 Kimal shall:

- (a) provide the Supplier with reasonable access at reasonable times to Kimal's premises for the purpose of providing the Services; and
- (b) provide such necessary information for the provision of the Services as the Supplier may reasonably request.

9. Charges and payment

9.1 The price for the Goods:

- (a) shall be the price set out in the Order, or if no price is quoted, the price set out in the Supplier's published price list in force at the Commencement Date; and
- (b) shall be inclusive of the costs of packaging, insurance and carriage of the Goods. No extra charges shall be effective unless agreed in writing and signed by Kimal.

9.2 For the avoidance of all doubt, once an Order has been placed, the Supplier shall not be entitled to change the price for the Goods without the prior agreement of Kimal.

9.3 The charges for the Services shall be set out in the Order, and shall be the full and exclusive remuneration of the Supplier in respect of the performance of the Services. Unless otherwise agreed in writing by Kimal, the charges shall include every cost and expense of the Supplier directly or indirectly incurred in connection with the performance of the Services.

9.4 In respect of the Goods, the Supplier shall invoice Kimal on or at any time after completion of delivery. In respect of Services, the Supplier shall invoice Kimal on completion of the Services. Each invoice shall include such supporting information required by Kimal to verify the accuracy of the invoice, including the relevant purchase order number.

9.5 In consideration of the supply of Goods and/or Services by the Supplier, Kimal shall pay the invoiced amounts within 30 days of the date of a correctly rendered invoice to a bank account nominated in writing by the Supplier.

9.6 All amounts payable by Kimal under the Contract are exclusive of amounts in respect of valued added tax chargeable from time to time (**VAT**). Where any taxable supply for VAT purposes is made under the Contract by the Supplier to Kimal, Kimal shall, on receipt of a valid VAT invoice from the Supplier, pay to the Supplier such additional amounts in respect of VAT as are chargeable on the supply of the Goods and/or Services at the same time as payment is due for the supply of the Goods and/or Services.

9.7 If a party fails to make any payment due to the other party under the Contract by the due date for payment, then the defaulting party shall pay interest on the overdue sum from the due date until payment of the overdue sum, whether before or after judgment. Interest under this clause will accrue each date at 2% a year above the Bank of England's base rate from time to time, but at 2% a year for any period when the base rate is below 0%. Where a payment is disputed in good faith, interest is only payable after the dispute is resolved, on sums found or agreed to be due, from the date on which the dispute is resolved until payment.

9.8 The Supplier shall maintain complete and accurate records of the time spent and materials used by the Supplier in providing the Services, and the Supplier shall allow Kimal to inspect such records at all reasonable times on request.

9.9 Kimal may at any time, without notice to the Supplier, set off any liability of the Supplier to Kimal against any liability of Kimal to the Supplier, whether either liability is present or future, liquidated or unliquidated, and whether or not either liability arises under the Contract. Any exercise by Kimal of its rights under this clause shall not limit or affect any other rights or remedies available to it under the Contract or otherwise.

10. Intellectual property rights

10.1 All Intellectual Property Rights in or arising out of or in connection with the Services shall be owned by Kimal. The Supplier shall complete all such actions as are required to assign such rights to Kimal.

10.2 Kimal grants the Supplier a fully paid-up, non-exclusive, royalty-free non-transferable licence to copy any materials provided by Kimal to the Supplier for the term of the Contract for the purpose of providing the Services to Kimal.

10.3 The Supplier acknowledges that all rights in Kimal Materials are and shall remain the exclusive property of Kimal.

11. Indemnity

11.1 The Supplier shall indemnify Kimal against all liabilities, costs, expenses, damages and losses (including any direct, indirect or consequential losses, loss of profit, loss of reputation and all interest, penalties and legal costs (calculated on a full indemnity basis) and all other reasonable professional costs and expenses) suffered or incurred by Kimal arising out of or in connection with:

- (a) any claim made against Kimal for actual or alleged infringement of a third party's intellectual property rights arising out of, or in connection with, the manufacture,

supply or use of the Goods, or receipt, use or supply of the Services (excluding Kimal Materials);

- (b) any investigation into Kimal by any Competent Authority which is directly attributable to any breach of Contract by the Supplier;
- (c) any recall or return of any Deliverables, whether or not such recall or return is at the request of the Supplier or Kimal;
- (d) any claim made against Kimal by a third party for death, personal injury or damage to property arising out of, or in connection with, defects in the Goods, as delivered, or the Deliverables; and
- (e) any claim made against Kimal by a third party arising out of or in connection with the supply of the Goods, as delivered, or the Services.

This clause **11** shall survive termination of the Contract.

12. Confidentiality

12.1 Each party undertakes that it shall not at any time during the Contract and for a period of two years after termination or expiry of the Contract, disclose to any person any confidential information concerning the business, affairs, customers, clients or suppliers of the other party, except as permitted by clause **12.2**.

12.2 Each party may disclose the other party's confidential information:

- (a) to its employees, officers, representatives, contractors, subcontractors or advisers who need to know such information for the purposes of exercising the party's rights or carrying out its obligations under the Contract. Each party shall ensure that its employees, officers, representatives, contractors, subcontractors or advisers to whom it discloses the other party's confidential information comply with this clause **12**; and
- (b) as may be required by law, a court of competent jurisdiction or any governmental or regulatory authority.

12.3 Neither party shall use the other party's confidential information for any purpose other than to exercise its rights and perform its obligations under or in connection with the Contract.

13. Compliance with relevant laws and policies

In performing its obligations under the Contract, the Supplier shall:

- (a) comply with all applicable laws, statutes, regulations and codes from time to time in force; and
- (b) comply with the Mandatory Policies.

Data protection

Both parties will comply with all applicable requirements of the Data Protection Legislation.

15. Audit

The Supplier shall allow access to Kimal and/or the relevant Competent Authority (as applicable) to the Supplier's technical documentation and records relating to the relevant Deliverables and promptly provide copies of such technical documentation and records to Kimal on request where this is needed for Kimal to comply with any laws. Including the Applicable Laws, or any requirements of a Competent Authority. Where required by Kimal, the Supplier shall grant access to and put in place appropriate procedures governing and facilitating access to the Supplier's premises in order for Kimal and/or the relevant Competent Authority (as applicable) to exercise its rights under this clause 15.1.

15.2 Kimal and/or an authorised representative of Kimal shall have the right to audit and inspect the Supplier's facilities, the equipment used in the processing, packaging, storage, testing, shipping or receiving of Deliverables, and any components used in the manufacture of Deliverables, in each case during normal business hours, upon reasonable notice and at such frequencies as Kimal may determine acting reasonably. The Supplier's representatives may be present at any such audit. Such audits may include, without limitation (i) initial baseline audits, (ii) for cause/event audits, (iii) audits in connection with the Device Regulations, and/or (iv) audits for special cases in which Kimal's representatives may be present during any processing of the Deliverables. During such visits (and other reasonable times), the Supplier shall ensure that Kimal, or authorised representatives will have access during audits to all documents, records, reports, data, procedures, facilities, regulatory submissions, and all other reasonable information related to the relevant Deliverables being processed.

The Supplier shall at all times co-operate with and assist with any request for information or queries raised by a Competent Authority in connection with relevant Deliverables and shall permit, authorised officials of any Competent Authorities or other competent governmental agencies to inspect its facilities, including the equipment, used for the processing, filling, packaging, storage, testing, shipping or receiving of Deliverables and/or any components or raw materials used in the manufacture or processing of the Deliverables, in each case as required or necessary for the granting or maintaining of any approval or product registration by such Competent Authority. The Supplier shall notify Kimal immediately upon receipt of any request for information or notice of inspection received from the Competent Authority in respect of Deliverables and shall provide copies of all correspondence between it and the Competent Authority relating to any adverse findings or non-compliance with Laws relating to the relevant Deliverables.

The rights under this clause shall survive for a period of 6 years post-termination.

16. Termination

16.1 Without affecting any other right or remedy available to it, Kimal may terminate the Contract:

- (a) with immediate effect by giving written notice to the Supplier if the Supplier commits a breach of clause **13**.
- (b) for convenience by giving the Supplier 1 months' written notice.

16.2 Without affecting any other right or remedy available to it, Kimal may terminate the Contract with immediate effect by giving written notice to Supplier if:

(a) the Supplier commits a material breach of any term of the Contract which breach is irremediable or (if such breach is remediable) fails to remedy that breach within a period of 14 days after being notified in writing to do so;

(b) the Supplier takes any step or action in connection with its entering administration, provisional liquidation or any composition or arrangement with its creditors (other than in relation to a solvent restructuring), obtaining a moratorium, being wound up (whether voluntarily or by order of the court, unless for the purpose of a solvent restructuring), having a receiver appointed to any of its assets or ceasing to carry on business or, if the step or action is taken in another jurisdiction, in connection with any analogous procedure in the relevant jurisdiction;

(c) the Supplier suspends, or threatens to suspend, or ceases or threatens to cease to carry on all or a substantial part of its business; or

(d) the Supplier's financial position deteriorates so far as to reasonably justify the opinion that its ability to give effect to the terms of this agreement is in jeopardy.

Any provision of the Contract that expressly or by implication is intended to come into or continue in force on or after termination or expiry of the Contract shall remain in full force and effect.

17. Force majeure

Neither party shall be in breach of the Contract nor liable for delay in performing, or failure to perform, any of its obligations under the Contract if such delay or failure results from events, circumstances or causes beyond its reasonable control. In such circumstances the affected party shall be entitled to a reasonable extension of the time for performing such obligations. If the period of delay or non-performance continues for 4 weeks, the party not affected may terminate the Contract by giving 7 days' written notice to the affected party.

General

18.1 Assignment and other dealings.

(a) Kimal may at any time assign, mortgage, charge, subcontract, delegate, declare a trust over or deal in any other manner with all or any of its rights and obligations under the Contract.

(b) The Supplier shall not assign, transfer, mortgage, charge, delegate, declare a trust over or deal in any other manner with any of its rights and obligations under the Contract without the prior written consent of Kimal.

18.2 **Subcontracting.** The Supplier may not subcontract any or all of its rights or obligations under the Contract without the prior written consent of Kimal. If Kimal consents to any subcontracting by the Supplier, the Supplier shall remain responsible for all the acts and omissions of its subcontractors as if they were its own.

18.3 **Severance.** If any provision or part-provision of the Contract is or becomes invalid, illegal or unenforceable, it shall be deemed deleted, but that shall not affect the validity and enforceability of the rest of this agreement. If any provision of the Contract is deemed deleted under this clause **18.3** the parties shall negotiate in good faith to agree a replacement provision that, to the greatest extent possible, achieves the intended commercial result of the original provision.

18.4 **Waiver.** Except as set out in clause **2.5**, no failure or delay by a party to exercise any right or remedy provided under the Contract or by law shall constitute a waiver of that or any other right or remedy, nor shall it prevent or restrict the further exercise of that or any other right or remedy. No single or partial exercise of such right or remedy shall prevent or restrict the further exercise of that or any other right or remedy.

18.5 **No partnership or agency.** Nothing in the Contract is intended to, or shall be deemed to, establish any partnership or joint venture between the parties, constitute either party the agent of the other, or authorise either party to make or enter into any commitments for or on behalf of the other party. Each party confirms it is acting on its own behalf and not for the benefit of any other person.

18.6 **Entire agreement.** The Contract constitutes the entire agreement between the parties and supersedes and extinguishes all previous agreements, promises, assurances, warranties, representations and understandings between them, whether written or oral, relating to its subject matter.

18.7 Third party rights.

(a) Unless it expressly states otherwise, the Contract does not give rise to any rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of the Contract.

18.8 **Variation.** Except as set out in these Conditions, no variation of the Contract, including the introduction of any additional terms and conditions, shall be effective unless it is agreed in writing and signed by the parties or their authorised representatives.

18.9 **Governing law.** The Contract, and any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with it or its subject matter or formation shall be governed by and construed in accordance with the law of England and Wales.

18.10 **Jurisdiction.** Each party irrevocably agrees that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with the Contract or its subject matter or construction.