

Kimal PLC – International Conditions of Sale

1 Interpretation

- 1.1 The definitions and rules of interpretation in this condition apply in these conditions.

Buyer: the person, firm or company who purchases the Products from Kimal.

Contract: a contract between Kimal and the Buyer for the sale and purchase of the Products in accordance with these conditions.

Kimal: Kimal PLC, a company incorporated in the United Kingdom under number 00827857 whose registered office address is at Unit 10A Clayfield Road, Worcester Six Business Park, Worcester, Worcestershire WR4 0AE.

Products: any goods (or part of them) to be supplied to the Buyer by Kimal as set out in the order.

- 1.2 A reference to legislation or a legislative provision is a reference to it as amended or re-enacted from time to time and includes all subordinate legislation made under that legislation or legislative provision.
- 1.3 Any words following the terms including, include, in particular, for example or any similar expression shall be interpreted as illustrative and shall not limit the sense of the words preceding those terms.
- 1.4 A reference to writing or written excludes fax but not email.

2 Application of Terms

- 2.1 The Contract shall be on these conditions to the exclusion of all other terms and conditions (including any terms or conditions which the Buyer purports to apply under any purchase order, confirmation of order, specification or other document, or which are implied by law, trade custom, practice or course of dealing).
- 2.2 These conditions apply to all Kimal's sales and except as provided for herein no variation to these conditions shall have any effect unless expressly agreed in writing and signed by an authorised representative of Kimal. Kimal may replace Schedule 1 with provisions required to bring this Contract into line with Device Regulations by giving notice to the Buyer and those updated terms shall automatically apply from the date of such notice.
- 2.3 The Buyer acknowledges that it has not relied on any statement or representation made by or on behalf of Kimal which is not set out in the Contract.
- 2.4 Each order for Products, or acceptance of a quotation by the Buyer, shall be deemed to be an offer by the Buyer to buy Products subject to these conditions. No order shall be deemed to be accepted by Kimal until:
- 2.4.1 a written acceptance of order is issued by Kimal; or
 - 2.4.2 (if earlier) Kimal starts production of the Products or delivers them,

at which point the Contract shall come into existence.

- 2.5 Kimal shall not accept or be obliged to fulfil orders:
- 2.5.1 whose value is less than USD \$500; or
 - 2.5.2 for Products in quantities other than their applicable box quantities.
- 2.6 The Buyer shall ensure that the terms of its order, including the description, code numbers and other details relating to the Products, and any applicable specification, are complete and accurate.
- 2.7 Any quotation is given on the basis that it does not constitute an offer. Any quotation is valid for a period of 90 days only from its date, or such other period as may be specified in the quotation, unless withdrawn by Kimal.
- 2.8 Any order placed by the Buyer with Kimal may not be cancelled except at Kimal's discretion. Any cancellation accepted by Kimal shall be subject to the payment by the Buyer of a cancellation fee equal to twenty-five per cent (25%) of the price of the relevant Products.
- 2.9 The quantity and description of the Products shall be as set out in Kimal's quotation or acceptance of order.
- 2.10 All samples, illustrations, descriptive matter, specifications and advertising issued by Kimal or contained in Kimal's catalogues or brochures are for the sole purpose of giving an approximate idea of the Products described in them. They shall not form part of the Contract and no sale of Products shall be a sale by sample. Kimal may make changes in the design or specification of its Products from time to time and without notice.
- 2.11 If the Buyer is appointed as Kimal's distributor of the Products then the Buyer may be subject to additional obligations (and in particular restrictions on the resale of Products) under the terms of any distribution agreement entered into with Kimal.

3 Price and payment

- 3.1 The price for the Products shall be as set out in Kimal's quotation (or otherwise in such price list as Kimal may make available to the Buyer).
- 3.2 Unless otherwise stated in writing by Kimal all prices quoted for Products shall be ex-works and shall be exclusive of VAT, United Kingdom export and overseas import duties, carriage costs, insurance costs, the costs of any work undertaken for the Buyer and any other ancillary costs, in respect of each of which Kimal shall be entitled to make additional charges where applicable.
- 3.3 Unless otherwise agreed, payment must be made in full before the Products are delivered by Kimal under clause 4, at the times and by the methods specified in Kimal's quotation or acceptance of order.
- 3.4 Payment shall be made in the currency of Kimal's quotation or price list and time for payment shall be of the essence.
- 3.5 The Buyer shall make all payments due under the Contract in full without any deduction or set-off whether by way of counterclaim or otherwise.

- 3.6 If the Buyer fails to pay Kimal any sum due pursuant to the Contract, the Buyer shall be liable to pay interest to Kimal on such sum from the due date for payment at the annual rate of 4% above the base lending rate from time to time of Barclay's Bank, accruing on a daily basis until payment is made, whether before or after any judgment.

4 Delivery

- 4.1 Unless otherwise agreed in writing by Kimal, the Products shall be delivered ex works (Incoterms 2020) at Kimal's warehouse, and unless another means of delivery has been expressly agreed "**delivering**" and "**delivery**" in these conditions means making the Products available for collection by the Buyer's nominated carrier.
- 4.2 Kimal will use reasonable endeavours to deliver the Products on such date(s) as Kimal stated in its order acceptance. Time for delivery shall not be of the essence of the Contract.
- 4.3 Kimal will notify the Buyer in advance of the date on which the Products will be delivered. The Buyer must provide instructions for shipping of the Products and arrange for their collection within fourteen (14) days after such date. If the Products are not collected within such period then Kimal may pack the Products and advise the Buyer of the packing details.
- 4.4 If the Buyer has not collected any Products within seven (7) days after being advised of their packing details under condition 4.3, then Kimal may at its option:
- 4.4.1 store the Products, in which case the Buyer shall pay Kimal's costs and expenses of doing so on demand (calculated at £2 GBP per pallet per day); and/or
 - 4.4.2 ship the Products to the Buyer at any time, in which case the Buyer shall pay Kimal's costs and expenses of doing so on demand.
- 4.5 Kimal may deliver the Products by separate instalments. Each separate instalment shall be invoiced and paid for in accordance with the provisions of the Contract. Each instalment shall be a separate Contract and no cancellation or termination of any one Contract relating to an instalment shall entitle the Buyer to repudiate or cancel any other Contract or instalment.

5 Non-delivery

- 5.1 The quantity of any consignment of Products recorded by Kimal on despatch shall be evidence of the quantity received by the Buyer unless the Buyer provides conclusive evidence to the contrary.
- 5.2 Kimal shall not be liable for:
- 5.2.1 any damage to the Products caused during transit (if shipping has been arranged by Kimal); or
 - 5.2.2 any shortfall in delivery of Products, unless the Buyer gives written notice to Kimal of the shortfall within three (3) days of receipt.
- 5.3 Any liability of Kimal for non-delivery or damage during transit shall be limited to replacing the relevant Products within a reasonable time or issuing a credit note for such Products at the pro rata Contract rate.

6 Risk/Title

- 6.1 The Products are at the risk of the Buyer from the time of delivery.
- 6.2 Ownership of the Products shall not pass to the Buyer until the later of delivery or when Kimal has received in full (in cash or cleared funds) all sums due to it in respect of the Products and all other sums which are or which become due to Kimal from the Buyer on any account.

7 Warranty

- 7.1 Subject as herein provided Kimal warrants to the Buyer all Products supplied under this Agreement will be of merchantable quality and will conform in all material respects with specifications provided by Kimal in relation to them.
- 7.2 In the event of any breach of Kimal's warranty in this condition (whether by reason of defective materials, production faults or otherwise) Kimal's liability shall be limited to:
- 7.2.1 replacement of the Products in question; or
- 7.2.2 at Kimal's option, repayment of the price (where this has been paid).
- 7.3 Where any Products are to be returned to Kimal, the Buyer shall ensure where appropriate that they are sterile.
- 7.4 The Buyer shall maintain adequate insurance against claims for damages and costs based on allegations that the Products or any of them are defective and shall provide Kimal on request with reasonable evidence of the terms of the insurance policy.
- 7.5 Kimal shall not be liable for a breach of any of the warranties in condition 7.1:
- 7.5.1 unless the Buyer gives written notice of the defect or non-conformity to Kimal within fourteen (14) days of delivery of the relevant Products in accordance with condition 4;
- 7.5.2 unless the Buyer (if asked to do so by Kimal) returns such Products to Kimal at Kimal's cost for examination;
- 7.5.3 if the Buyer makes any further use of the Products after giving such notice;
- 7.5.4 if the defect arises because the Buyer failed to follow Kimal's oral or written instructions (or good trade practice) as to the storage or use of the Products; or
- 7.5.5 if the Buyer alters or repairs such Products without Kimal's consent.
- 7.6 If Kimal complies with condition 7.2 it shall have no further liability for a breach of any of the warranties in condition 7.1 in respect of such Products.
- 7.7 All warranties, conditions and other terms implied by statute or common law (save for the conditions implied by section 12 of the Sale of Goods Act 1979 and section 13 of the Supply of Products and Services Act 1982) are, to the fullest extent permitted by law, excluded from the Contract.

8 Returns

- 8.1 Kimal may at its option accept the return of Products which are within their original unopened packaging and in first class condition, provided that the Buyer's return request is notified to Kimal within three (3) months after the date of delivery.
- 8.2 If Kimal accepts the Buyer's return request, then Kimal will issue an authorised return number which the Buyer must quote on the return shipment (which will be at the Buyer's cost).
- 8.3 Returned Products will be inspected by Kimal within a reasonable period of receipt. If Kimal accepts the returned Products then Kimal will give the Buyer credit against future purchases of Products to the value of seventy-five per cent (75%) of the price paid by the Buyer for the returned Products.

9 Limitation of liability

- 9.1 Subject to conditions 5 and 7 the following provisions set out the entire financial liability of Kimal (including any liability for the acts or omissions of its employees, agents and subcontractors) to the Buyer in respect of:
- 9.1.1 any breach of these conditions;
 - 9.1.2 any use made or resale by the Buyer of any Products; and
 - 9.1.3 any representation, statement or tortious act or omission including negligence arising under or in connection with the Contract.
- 9.2 Nothing in these conditions excludes or limits the liability of Kimal for any matter in relation to which it would be illegal for Kimal to exclude or attempt to exclude its liability.
- 9.3 Subject to condition 9.2:
- 9.3.1 Kimal's total liability in contract, tort (including negligence or breach of statutory duty), misrepresentation, restitution or otherwise, arising in connection with the performance or contemplated performance of the Contract shall be limited to the Contract price; and
 - 9.3.2 Kimal shall not be liable to the Buyer for:
 - (i) any loss of profit, loss of business, or depletion of goodwill (in each case whether direct or indirect); or
 - (ii) any indirect or consequential loss,in each case arising out of or in connection with the Contract or its subject matter.

10 Termination

- 10.1 If the Buyer fails to make any payment to Kimal on the due date under the Contract or any other contract between Kimal and the Buyer, Kimal will be entitled to suspend any further deliveries to the Customer pending receipt of payment.

- 10.2 Without limiting its other rights or remedies, either party may terminate the Contract with immediate effect by giving written notice to the other party if:
- 10.2.1 the other party commits a material breach of this Contract and (if such breach is remediable) fails to remedy that breach within a period of 30 days after being notified in writing to do so; or
 - 10.2.2 the other party ceases or threatens to cease to trade, becomes insolvent or is the subject of insolvency proceedings, makes an arrangement or composition with its creditors, has a receiver and/or administrator appointed over its undertaking or is the subject of any similar or equivalent action or occurrence.
- 10.3 Any provision of this Contract that expressly or by implication is intended to come into or continue in force on or after termination shall remain in full force and effect, including Schedule 1.

11 Anti-bribery Policy

- 11.1 Policy Summary - Kimal recognises the moral, economic and reputational risks associated with bribery and corruption, and has adopted a zero tolerance policy. The company prohibits bribery of any form, and will not tolerate its directors, managers, employees and any third parties involved in its business activities being involved in bribery, and expects them (i) not to offer or make any bribe, unorthodox or unauthorised payment or inducement of any kind to anyone (ii) not to solicit business, or business advantage, by offering any bribe, unorthodox or unofficial payment to customers or potential customers (iii) not to accept any kind of bribe, unorthodox or unusual payment or inducement that would not be authorised in the ordinary course of business (iv) to refuse any bribe or unorthodox payment and to do so in a manner that is not open to misunderstanding or giving rise to false expectation and (v) to report any perceived breach of this policy.
- 11.2 The Buyer shall therefore:
- 11.2.1 comply with all applicable laws, statutes, regulations and codes relating to anti-bribery and anti-corruption including but not limited to the Bribery Act 2010 ("Relevant Requirements");
 - 11.2.2 Not engage in any activity, practice or conduct which would constitute an offence under sections 1, 2 or 6 of the Bribery Act 2010 if such activity, practice or conduct had been carried out in the UK;
 - 11.2.3 comply with Kimal's Anti-corruption and Bribery policy and any relevant industry code on anticorruption and bribery, in each case as Kimal or the relevant industry body may update them from time to time (available upon request) ("Relevant Policies");
 - 11.2.4 have and shall maintain in place throughout the term of this Contract its own policies and procedures, including but not limited to adequate procedures under the Bribery Act 2010, to ensure compliance with the Relevant Requirements and the Relevant Policies, and will enforce them where appropriate;

- 11.2.5 promptly report to Kimal any request or demand for any undue financial or other advantage of any kind received by the Buyer which would qualify as a breach of Kimal's policy as set out in this condition 11;
 - 11.2.6 immediately notify Kimal (in writing) if a foreign public official becomes an officer or employee of the Buyer or acquires a direct or indirect interest in the Buyer (and the Buyer warrants that it has no foreign public officials as officers, employees or direct or indirect owners); and
 - 11.2.7 shall promptly provide such supporting evidence of compliance with this clause as Kimal may reasonably request.
- 11.3 The Buyer shall ensure that any person associated with the Buyer who is performing services or providing goods in connection with the Products does so only on the basis of a written contract which imposes on and secures from such person terms equivalent to those imposed on the Buyer in this condition 11. The Buyer shall be responsible for the observance and performance by such persons and shall be directly liable to Kimal for any breach by such persons.
- 11.4 Breach of this condition 11 shall be deemed a material breach and allows Kimal to terminate all activities with the Buyer with immediate effect.
- 11.5 For the purpose of this condition 11, the meaning of adequate procedures and foreign public official and whether a person is associated with another person shall be determined in accordance with section 7(2) of the Bribery Act 2010 (and any guidance issued under section 9 of that Act), sections 6(5) and 6(6) of that Act and section 8 of that Act respectively. For the purposes of this condition 11 a person associated with the Buyer includes but is not limited to any subcontractor of the Buyer.

12 Anti-Slavery and Human Trafficking

- 12.1 The Buyer shall:
- 12.1.1 comply with all applicable anti-slavery and human trafficking laws, statutes, regulations and codes from time to time in force, including but not limited to the Modern Slavery Act 2015; and
 - 12.1.2 comply with the Modern Slavery Statement available on Kimal's website from time to time in relation to its activities performed under or in connection with this Contract.
- 12.2 Breach of this condition 12 shall be deemed a material breach and allows Kimal to terminate all activities with the Buyer with immediate effect.

13 Technical Agreement

- 13.1 The Buyer shall:
- 13.1.1 comply with the terms of Schedule 1, which is incorporated in and forms part of the Contract;

- 13.1.2 ensure that, should the Products be of a medicinal nature, the Buyer holds the relevant licenses to comply with the requirements for these Products; and
- 13.1.3 give consideration to the environmental impact of their business and if appropriate develop an environmental policy.

14 General

- 14.1 Kimal may defer the date of delivery, cancel the Contract or reduce the volume of Products ordered by the Buyer (without liability to the Buyer) if it is prevented from or delayed in making or delivering the Products due to circumstances beyond its reasonable control, including (without limitation) acts of God, war or national emergency, terrorism, civil commotion, fire, explosion, flood, labour disputes, or shortages of materials.
- 14.2 The Buyer may not assign any of its rights under the Contract without Kimal's written consent.
- 14.3 If any provision or part-provision of the Contract is found by any court of competent jurisdiction to be wholly or partly illegal, invalid, void, or unenforceable it shall be deemed severable and the other provisions of the Contract and the remainder of such provision shall continue in full effect.
- 14.4 Any waiver by Kimal of any breach of any provision of the Contract by the Buyer must be in writing and shall not be deemed a waiver of any subsequent or other breach.
- 14.5 No term of the Contract shall be enforceable under the Contracts (Rights of Third Parties) Act 1999 by any person that is not a party to it.
- 14.6 This Contract and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with English law, and the parties submit to the exclusive jurisdiction of the English courts.
- 14.7 All notices under the Contract shall be in writing and delivered by hand or sent by pre-paid first class post to the registered office of the receiving party or to such other address or by such other means as shall be notified by the receiving party.

Schedule 1

1.0 DEFINITIONS

1.1 For the purposes of this Schedule 1, the following definitions shall apply:

“Adverse Event”	means 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;
“Competent Authority”	means any federal, state, local, supranational or international regulatory agency, department, bureau, or other governmental entity which is responsible for issuing approvals, licenses, registrations, clearances or authorizations necessary for the manufacture, use, storage, import, transport, offering for sale or sale of the Products in a regulated jurisdiction, 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;
“Complaint”	means any written, electronic or oral communication that alleges deficiencies relating to the identity, quality, durability, reliability, safety, effectiveness or performance of a device released for human use;
“Customer Feedback”	means any non-positive form of communication (whether written, electronic, oral or any other form of communication) from a customer, regarding: i) a Product (which may or may not be comparative in nature); or ii) procedural outcome relating to the use of any Product;
“Device Regulations”	means all applicable laws and regulations applying to the manufacture, import, distribution, marketing and supply of medical devices, including the UK Medical Device Regulations 2002 the EU Medical Device Regulation 2017/745 and any national laws in the territory in which the buyer is operating and any applicable industry codes and standards including EN ISO 13485 / EN ISO 9001;
“Serious Adverse Event”	means any Adverse Event that led to any of the following: • death; • serious deterioration in the health of the subject, that resulted in any of the following: ○ life-threatening illness or injury; ○ permanent impairment of a body structure or a body function;

- hospitalisation or prolongation of patient hospitalisation;
- medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function;
- chronic disease; or
- foetal distress, foetal death or a congenital physical or mental impairment or birth defect;

2.0 GENERAL COMPLIANCE OBLIGATIONS

2.1 The Buyer shall:

- 1.1.1 at all times comply with its obligations under Device Regulations;
- 1.1.2 ensure that all activities relating to the Products are performed by personnel who are appropriately trained and/or qualified for the activity being performed;
- 1.1.3 ensure that, while the Products are under its responsibility, the storage and/or transport conditions comply with any requirements communicated to it by Kimal;
- 1.1.4 not supply or otherwise provide any Product to any third party outside of their expiration date;
- 1.1.5 co-operate at all times with Kimal to achieve an appropriate level of traceability of Products, including by responding to requests on traceability within 24 hours;
- 1.1.6 co-operate and communicate with Kimal on any matter which relates to product safety and product quality in relation to the Products; and
- 1.1.7 not modify any Products, their packaging or labelling in any way, without the prior written agreement of Kimal.

3.0 QUALITY MANAGEMENT

- 3.1 The Buyer shall ensure that it has in place a quality management system that includes, without limitation, procedures which ensure that the translation of information is accurate and up-to date and performed in such a way that preserve the original condition of the Product and that the packaging of any repackaged Product is not defective, of poor quality or untidy.
- 3.2 Before supplying a Product to any third party, the Buyer shall have a system in place to verify that all of the following requirements are met:

- 3.2.1 the Product complies with the requirements of the Device Regulations, including where applicable that the Product has been appropriately marked and relevant conformity declarations drawn up;
 - 3.2.2 the Product is accompanied by such information as is required to be supplied by the manufacturer in accordance with the Device Regulations;
 - 3.2.3 where applicable, a unique device identifier (UDI) has been assigned by the manufacturer.
- 3.3 In the event that the Buyer has reason to believe that a Product is not in conformity with the applicable Device Regulations, it shall inform Kimal immediately. The Buyer shall co-operate with Kimal, to ensure that the necessary corrective action to bring that Product into conformity, to withdraw or to recall it, as appropriate, is taken. Kimal agrees to notify the Buyer of any requirement for a field safety correction action affecting the Products. The Buyer shall comply with Kimal's instructions in relation to field actions.
- 3.4 The Buyer shall place Product(s) on hold at the Buyer's facility on request from Kimal and co-operate with Kimal in relation to any Product(s) placed on hold. Where the Buyer considers a Product to be defective in any way, it shall place the device on hold and communicate the issue to Kimal immediately. The Buyer shall not release the affected Product until receiving written approval to do so from Kimal.

4.0 COMPLAINTS

- 4.1 The Buyer shall immediately:
- 4.1.1 forward any Complaint relating to any Products to Kimal;
 - 4.1.2 communicate any information it receives relating to, or alleging, a defect in any Product, or any Adverse Event, including any Serious Adverse Event,
- to vigilance@kimal.co.uk via email or by any other appropriate means.
- 4.2 The Buyer shall keep a register of Customer Feedback/Complaints, of non-conforming Products and of recalls and withdrawals, and keep Kimal informed of such monitoring and provide the Supplier with any information upon request.
- 4.3 The Buyer shall comply with Kimal's instructions as they relate to the handling of Complaints.

5.0 EU MEDICAL DEVICE REGULATION REQUIREMENTS

- 5.1 Where the EU Medical Device Regulations 2017/745 ("MDR") apply, the Buyer shall, in addition to the general obligations contained in this Schedule 1, comply with the provisions of this paragraph 5.0.
- 5.2 The Buyer shall comply with the requirements applicable to it under the MDR. Without limiting the foregoing, where the Buyer is an importer, it shall:
- 5.2.1 register with the relevant Competent Authority;

- 5.2.2 verify a manufacturer is identified and an authorised representative has been designated in relation to the Product;
- 5.2.3 ensure the Product is labelled and accompanied by instructions for use as required under the MDR;
- 5.2.4 indicate the Buyer's name, place of business and contact details in a way so as not to obscure any information on the label for the Product.
- 5.3 Where the Buyer is a distributor, is shall comply with paragraph 5.2 and additionally ensure that the importer has complied with the requirements in Article 13(3) MDR.
- 5.4 The Buyer shall be able to identify the following to the Competent Authority, for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market (or at least 15 years for implantable devices):
 - 5.4.1 any economic operator (within the meaning of the MDR) to whom they have directly supplied a device;
 - 5.4.2 any economic operator who has directly supplied them with a device; and
 - 5.4.3 any health institution or healthcare professional to which they have directly supplied a device.

6.0 RECORDS AND REPORTING

- 6.1 The Buyer shall:
 - 6.1.1 maintain records of all Product supplied by it for a period of 10 years (or 15 years for implantable Products) using the Kimal lot number, quantities of units and locations to where such units were supplied (full address and facility);
 - 6.1.2 make copies of the records maintained pursuant to this Schedule 1 available to Kimal on request;
 - 6.1.3 provide Kimal with post-market surveillance, in the form of clinical follow up, Competent Authority reports, training feedback and vigilance reports; and
 - 6.1.4 allow Kimal, or an authorized representative of Kimal, the right to perform audits on the facilities, systems, documents and other items related to the Buyer and the Products.