

## **General Terms and Conditions of Business**

**Version of June 2018**

### **01 Validity and Scope of Application**

These General Terms and Conditions of Business (hereinafter referred to as the "GTB") shall govern all business relations between KLK Kolb Specialties B.V. (hereinafter jointly or severally referred to as "KLK Kolb Specialties") and any co-contracting party (hereinafter referred to as the "Customer", regardless of any other denomination in other or additional contracting documents). The GTB form an integral part of the contractual relationship, become part of the contract once the Customer has been notified and the contract has been concluded and are applicable thereafter to each contract that is concluded between KLK Kolb Specialties and the Customer. Any other terms of business are not recognised unless KLK Kolb Specialties has approved them in writing. The GTB remain valid even if KLK Kolb Specialties fulfils the Customer's order without reservation despite being aware of the Customer's varying terms of business. Should individual provisions of these GTB be or become invalid or contain a loophole, the obligations imposed by the remaining provisions shall not be affected. Invalid sections shall be replaced with valid provisions that correspond as closely as possible to the legal and economic purpose of the invalid provision. The same procedure shall be followed if loopholes are found to exist in the contract.

### **02 Quotation, Order and Conclusion of Contracts**

Any quotations made by KLK Kolb Specialties as well as any information on price, quality, delivery date and availability of goods (hereinafter referred to as "Goods", regardless of any other denomination in other or additional contracting documents and including technical materials, as defined below) are non-binding unless otherwise confirmed in writing by KLK Kolb Specialties. A binding quotation is valid for 30 (thirty) days unless otherwise stated in writing by KLK Kolb Specialties. A contract is deemed to have been concluded when KLK Kolb Specialties confirms the Customer's order in writing or fulfils the order.

### **03 Delivery/Fulfilment of Contracts**

Any quotation and confirmation issued by KLK Kolb Specialties shall specify the scope and details of the delivery of Goods. The particular size and weight of the delivery shall conform to the sizes and weights determined by KLK Kolb Specialties and stated in the delivery documentation (which consists of, without limitation, (i) the material safety data sheet (referred hereinafter to as the "MSDS" or "Material Safety Data Sheet"), (ii) the technical data sheet (referred hereinafter to as the "TDS" or "Technical Data Sheet")). The Goods are deemed to be in accordance with the contract provided that the maximum negative difference is no greater than 1.5% for a nominal filling weight of 1-15 kg and no greater than 1% for a nominal filling weight of more than 15 kg. Any delivery shall be made at the Customer's expense and to the Customer's address unless a special place of delivery is agreed upon by both parties or arises due to the nature of the transaction. Partial deliveries may be made unless otherwise agreed in writing. Delivery dates shall only be binding if they have been agreed in writing. If KLK Kolb Specialties is unable to meet delivery dates, KLK Kolb Specialties must inform the Customer without delay and has the right to be granted an appropriate grace period. Compensation for any late delivery is excluded. The benefit and risk shall be transferred to the Customer when the delivery is made.

### **04 Technical Material**

The Customer and KLK Kolb Specialties may agree on the delivery of technical instruments, equipment or spare parts (hereinafter jointly referred to as the "Technical Material"). Technical Material shall be installed by KLK Kolb Specialties, if agreed in writing. Delivery and/or installation shall be carried out in compliance with the instructions of the manufacturer. Ownership of Technical Material shall be transferred to the Customer unless otherwise agreed in writing. The benefit and risk shall be transferred to the Customer when the delivery is

made. The operation and monitoring shall be of the responsibility of the Customer at all times. The Customer shall acknowledge that a system can only operate properly if no modification is made to the Technical Material and installation, it is not used or handled in an inappropriate manner or used contrary to the manufacturer's instructions. The Customer shall further acknowledge that Technical Material can also only operate properly if products recommended by KLK Kolb Specialties are used, if MSDS, and TDS are followed and if the recommended maintenance work is performed.

#### **05 Supporting advice**

Supporting advice on the use and application of the Goods and/or Technical Material, which is made available by KLK Kolb Specialties, together with sales advice, are provided with due care. However, advice does not release the Customer from its responsibility to have the Goods and/or Technical Material examined by an expert with regard to their suitability for the in-tended application.

#### **06 Payment**

Invoices shall be paid in full within the terms stated. Discounts may not be deducted unless this has been expressly agreed in writing by KLK Kolb Specialties. The terms of payment shall be 30 (thirty) days from the date of invoice unless otherwise agreed. Should the Customer not meet the payment deadline, the Customer is deemed to be in arrears, irrespective of any reminder, and must pay interest on these arrears amounting to 4 (four) percent above the prevailing discount rate of the National Bank of Switzerland, subject to a minimum of 5 (five) percent per annum. In the event that the Customer defaults on the payment, KLK Kolb Specialties has the right to withdraw from the contract (and, for the avoidance of doubt, any other business relation) without further notice and to demand compensation. Payment shall be made by bank transfer. Payment is deemed to be made when the amount has been credited to KLK Kolb Specialties's bank account in full and irrevocably. Cheques and bills of exchange shall not be accepted as means of payment.

#### **07 Use for Intended Purpose**

Unless otherwise agreed in writing, the Customer shall ensure that all Goods or parts thereof is used for intended pur-*pose* (hereinafter referred to as "Use for Intended Purpose") as specified in the respective Technical Data Sheet. Any other use is not allowed and constitutes an infringement of Use for Intended Purpose and results in a violation of the present GTB and any relating contract. Unless explicitly so stated in the Technical Data Sheet, the Use for Intended Purpose of any Goods or parts thereof, including any Goods processed shall in no event include pharmaceutical use (hereinafter referred to as "Pharmaceutical Use", which is defined as

(i) the use as active pharmaceutical ingredient [hereinafter referred to as "API"], i.e., a substance or mixture of sub-*stances* intended for use in the manufacture of a drug [medicinal] product and that, when used in the production of a drug, becomes an active ingredient of the drug product; such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the body of man or animals,

(ii) the use as excipient [hereinafter referred to as "Excipient"], i.e., a substance other than an API which is intentionally included in a drug delivery system and is appropriately evaluated for safety, and

(iii) for the avoidance of doubt, the use in any of the following: blood purification; medication such as contraceptive, eye drops, or nose drops; pharmaceutical salve; tablets, vaccines, wound treatment; parenteral applications; diagnostics in vitro and in vivo; food supplement; animal health).

KLK Kolb Specialties and the Customer note that Goods have neither been evaluated appropriately for safety as API nor as Excipient. The Parties note that according to regulatory standards, Excipients can only be pharmaceutical grade when in compliance with pharmacopeial specification and/or appropriate regulatory requirements (if existing for the specific Excipient) and manufactured, repackaged, and handled in accordance

with excipient good manufacturing practices and/or good distribution practices. The Parties note in particular that according to regulatory standards, upgrading technical or industrial material to pharmaceutical grade quality only on the basis of analytical results found in conformance with the requirements of a pharmacopeial monograph is an unacceptable practice. Exceptions must be granted by KLK Kolb Specialties in writing; such exceptions will not be unreasonably withheld. The Customer shall ensure that any of its co-contractors (e.g., buyer/manufacture or reseller) shall be under the same obligation, i.e., the Customer shall commit any of his co-contractors to ensure the Use for Intended Purpose of the Goods or parts thereof accordingly and to indemnify KLK Kolb Specialties for infringements thereof. This obligation shall also apply to (i) any Goods or parts thereof which are processed, including processing by co-contractors or third parties and (ii) any Goods or parts thereof resold to further co-contractors or third parties. The Customer shall communicate to KLK Kolb Specialties a person in charge who will act as contact person for the execution of present provision.

#### **08 Traceability**

The Customer shall organize a system based on KLK Kolb Specialties's unique identification code (hereinafter referred to as the "Unique identification Code") which secures that (i) the whereabouts as well as the, (ii) distribution line as well as the (iii) end use of each Good or parts thereof can be established at any time. The Customer shall ensure that any of its co-contractors (e.g., buyer/manufacture or reseller) shall be under the same obligation, i.e., the Customer shall commit any of its co-contractors to trace any Goods or parts thereof accordingly and to indemnify KLK Kolb Specialties for infringements thereof. This obligation shall also apply to (i) Goods or parts thereof which are processed, including processing by co-contractors or third parties and (ii) Goods or parts thereof resold to further co-contractors or third parties. The Customer shall communicate to KLK Kolb Specialties a person in charge who will act as contact person for the execution of the present provision.

#### **09 Delivery Stop / Recall**

Upon KLK Kolb Specialties's request, the Customer shall immediately stop delivery (hereinafter referred to as a "Delivery Stop") of, or recall (hereinafter referred to as "Recall"), certain Goods. In case of Recall or Delivery Stop KLK Kolb Specialties reserves the right at its own discretion to either replace the Goods or refund the price paid by the Customer. All further claims of the Customer are excluded. The Customer shall ensure that any of its co-contractors (e.g., buyer/manufacture or reseller) shall be under the same obligation, i.e., the Customer shall commit any of its co-contractors to adhere to a Delivery Stop or a Recall and to indemnify KLK Kolb Specialties for infringements thereof. This obligation shall also apply to (i) any Goods or parts thereof which are processed, including processing by co-contractors or third parties and (ii) Goods or parts thereof resold to further co-contractors or third parties. If the Customer fails to duly perform its obligations in the case of Recall or Delivery Stop, KLK Kolb Specialties reserves the right to undertake the necessary steps on its own or by third parties at the Customer's cost. KLK Kolb Specialties reserves the right to compensation for further damages. The Customer shall communicate to KLK Kolb Specialties a person in charge who will act as contact person for the execution of the present provision.

#### **10 Defects**

If an actual or possible defect of Goods, and for the avoidance of doubt also in case of Goods or parts thereof processed by third parties, has become known to the Customer, the Customer shall notify KLK Kolb Specialties in writing or by fax without delay. The Customer shall after consultation with KLK Kolb Specialties take all necessary steps (such as, e.g., but not limited to, Delivery Stop or Recall) to prevent any further use, including, but without limitation to, delivery, processing, and end use, of any concerned Goods or parts thereof. The

Customer shall ensure that any co-contractor (e.g., buyer/manufacturer or re-seller) shall be under the same obligation, i.e., the Customer shall commit any of its co-contractors to notify the Customer accordingly and to abide by steps ordered by KLK Kolb Specialties and to indemnify KLK Kolb Specialties for infringements thereof. This obligation shall also apply to (i) any Goods of parts thereof which are/is processed by, including processing by co-contractors or third parties and (ii) any Goods or parts thereof resold to further co-contractors or third parties. The Customer shall communicate to KLK Kolb Specialties a person in charge who will act as contact person for the execution of the present provision.

### **11 Warranty**

The Customer shall examine the delivered Goods without delay and report any defects in writing within 5 (five) days of receipt. Hidden defects should be reported in writing within 5 (five) days of their detection, at the latest, however no later than 6 (six) months following receipt of the Goods. Should the Customer not make such a report, or fail to do so within the time limits prescribed above, the delivered Goods shall be considered free of any defects and approved in all their functions. KLK Kolb Specialties warrants that the Goods supplied are at the time of delivery free from defects in material and workmanship. As the Customer's sole and exclusive remedy under this warranty, KLK Kolb Specialties agrees to replace any Goods which prove to be defective provided that complaints against Goods have been lodged within the time period set forth above. Goods against which complaints are lodged must be separated from any other material. This warranty is exclusive and is in lieu of all warranties of merchantability, fitness for purpose, or other warranties of quality, whether express

or implied. KLK Kolb Specialties shall in no event be liable for use of the Goods in violation of Section 07 and in case of Technical Material and installations, the warranty, if any, given by the manufacturer or supplier of such Technical Material shall be the only and sole remedy available to the Customer. KLK Kolb Specialties shall accept no responsibility for the operation and monitoring of Technical Material and installations. In the event of failure to comply with the law, the contract, these GTB or the separate conditions, recommendations and directives referred to therein, all warranty and liability on the part of KLK Kolb Specialties shall cease to apply.

### **12 Breach of Contract by the Customer**

In case of infringement of any of the provisions of the GTB or any of the other documents constituting the contractual relationship (including but not limited to a sales contract or framework agreement) (hereinafter referred to as a "Breach of Contract"), by the Customer or any of the Customer's co-contractors, (i) KLK Kolb Specialties shall not be liable and (ii) be under no duty to further perform any of its obligations. KLK Kolb Specialties may in case of Breach of Contract (i) terminate the business relationship and any contractual obligation in connection therewith and (ii) shall have the right to claim damages incurred by itself or third parties. KLK Kolb Specialties reserves the right to claim damages for, and the Customer undertakes to indemnify and hold KLK Kolb Specialties, its affiliates, employees and agents harmless against any damages or loss incurred, including damages incurred by third parties, arising out of, or resulting from, a Breach of Contract, including, but without limitation to any infringement on the Use for Intended Purpose by the Customer or its co-contractors.

### **13 Force Majeure**

KLK Kolb Specialties shall not be responsible for failure to fulfil its contractual obligations or for delays based on reasons that are not under control respectively in the sphere of power of KLK Kolb Specialties including, but not limited to: accidents, fire, explosions, flood, strikes or labour disputes, exclusions, sabotage, public disturbances, war or civil war, blockades, restrictions by authorities, impossibility of procurement of material or of procurement of transports as well as all other reasons of unforeseeable event. In such a case the duty of KLK Kolb Specialties shall be suspended as long as the event preventing KLK Kolb Specialties from fulfilling its contractual obligations lasts. Partial performance regarding products or services under the contract not

affected by an event of force majeure by KLK Kolb Specialties is allowed and shall be accepted by the Customer. If the event of force majeure lasts more than 90 (ninety) days, the Parties shall be allowed to renounce the fulfilment of the contract according to the unforeseeable event. In this case, the renouncing party shall inform the other party in writing or by fax. The Parties shall have no other rights than the said right to renounce. In no event shall KLK Kolb Specialties be obligated to replace or to substitute performance under the contract nor shall KLK Kolb Specialties be held responsible for nonfulfillment of the contract because of an event of force majeure.

#### **14 Limitation of Liability**

KLK Kolb Specialties shall not be liable for special, indirect, incidental or consequential damages such as, but not limited to, loss of profits or revenue, damage or loss of other property or equipment or cost of capital. The remedies of the Customer set forth herein are exclusive, and KLK Kolb Specialties's liability with respect to any contract or sale or anything done in connection there-with, whether in contract, in tort, under any warranty, or otherwise, shall not, except as expressly provided herein, exceed the amount of the payments received hereunder during the preceding year. Except in the event of gross negligence and intent, the Customer shall have no right to claim any damages.

#### **15 Data protection**

The Customer shall agree to the processing, storage and use of any of his personal data that is required for the fulfilment of an order.

#### **16 Retention of title**

Goods that have been purchased by the Customer shall remain the property of KLK Kolb Specialties even after delivery until payment has been made in full. If requested, the Customer shall undertake to support KLK Kolb Specialties in all actions to protect the ownership (e.g. an entry in the registry of proprietary rights). The Customer is obliged to inform KLK Kolb Specialties without delay in the event of seizure or any other form of confiscation by a third party.

#### **17 Applicable Law/Place of Jurisdiction**

Netherlands law shall apply exclusively to the exclusion of the Vienna Convention on Contracts for the International Sale of Goods 1980 (CISG) and the provisions of the LUVI - Uniform Act on International Sale (The Hague, July 1, 1964). The place of jurisdiction is court of the place of registration of KLK Kolb Specialties B.V.; KLK Kolb Specialties is, however, also entitled to bring a claim against the Customer at its registered office or place of business.