

effective from 10<sup>th</sup> of July, 2026

## 1. General

- 1.1. The "Seller" means the Institute of Isotopes Co. Ltd. (hereinafter, the "Seller"). All offers, sales and deliveries are subject exclusively to the following conditions, unless otherwise expressly agreed in writing. Business conditions of the Buyer that conflict with these conditions shall only become part of the contract if expressly accepted in writing by the Seller.
- 1.2. By submitting a purchase order to the Seller, the Buyer acknowledges that it has read, understood and accepted these General Conditions of Sale and Delivery (hereinafter, the "General Conditions"), and agrees to be legally bound by them. Any purchase order submitted by the Buyer shall constitute unconditional acceptance of these General Conditions unless otherwise expressly agreed by the Seller in writing.
- 1.3. Conditions not regulated herein shall be governed by Hungarian law and applicable EU regulations.

## 2. Validity of the Offer, Order Acknowledgement

- 2.1. All offers issued by the Seller are valid for thirty (30) calendar days or for the period stated in the offer.
- 2.2. Orders shall be deemed accepted upon written confirmation by the Seller or upon dispatch of the goods.
- 2.3. The Seller reserves the right, at its sole discretion, to modify, alter, improve, change or discontinue any Product.

## 3. Electronic Communications

- 3.1. The Parties agree that notices, approvals, confirmations, invoices, purchase orders and other communications transmitted by e-mail or other commonly used electronic means shall satisfy any requirement for written communication under these General Conditions, unless mandatory law requires otherwise.

## 4. Prices and Extra Costs

- 4.1. Prices are net, in the agreed currency.
- 4.2. The Seller reserves the right to adjust, modify or change prices at any time due to changes in market conditions, including but not limited to increases in the cost of raw materials, energy, transportation, labour, taxes, duties or regulatory compliance costs. If agreed in writing by both Parties, additional costs may be charged for:
  - Handling costs for shipments below EUR 500,
  - Certificate of Origin / EUR1 (if requested),
  - Datalogger for temperature control.

## 5. Dispatch

- 5.1. Goods are shipped at the Buyer's risk, even if transport charges are borne by the Seller or delivery is made free of charge. The Seller shall not be liable for any loss occurring during transportation.
- 5.2. All forwarding instructions must be provided together with the order. Any additional costs (e.g. express delivery) requested by the Buyer shall be borne by the Buyer.
- 5.3. Incoterms (e.g. EXW, FCA, CIF) shall be interpreted in accordance with INCOTERMS® 2020.

## 6. Delivery

- 6.1. Delivery dates are indicated in good faith. However, the Seller reserves the right to modify delivery dates and shall inform the Buyer without undue delay.
- 6.2. The Seller shall not be liable for any direct or indirect loss or damage resulting from delays, regardless of the cause.
- 6.3. Delivery dates are estimates only and shall not be of the essence unless expressly agreed otherwise in writing.

- 6.4. Partial deliveries shall be permitted unless otherwise expressly agreed in writing by the Parties.

## 7. Packaging

- 7.1. Goods supplied in returnable containers shall be returned to the Seller at the Buyer's expense, in good condition and within the period specified by the Seller.
- 7.2. Unless otherwise agreed, returnable containers are provided free of charge for thirty (30) calendar days. Thereafter, a rental fee may be charged depending on the container type.

## 8. Reservation of Title

- 8.1. The Seller retains ownership of the goods until the Buyer has fully performed all payment obligations arising from the relevant transaction, notwithstanding delivery.
- 8.2. If the applicable law of the country where the goods are located does not permit retention of title, the Seller shall be entitled to request equivalent security.

## 9. Payment

- 9.1. Unless otherwise agreed, all invoices are payable in full, without deductions, by bank transfer in the invoiced currency.
- 9.2. If agreed, the payment terms shall be thirty (30) calendar days from invoice date.
- 9.3. The Seller may require irrevocable, confirmed L/C depending on transaction value.
- 9.4. If the Buyer is in default of payment for more than fifteen (15) calendar days, the Seller may charge default interest at the rate of 0.1% of the outstanding amount per calendar day, without prejudice to any statutory default interest or other remedies available under applicable law.
- 9.5. The Seller may additionally claim any statutory default interest and other remedies available under the applicable law.
- 9.6. The Seller reserves the right to suspend further deliveries, withhold performance and/or terminate any outstanding orders until full payment has been received.
- 9.7. All bank charges outside the Seller's bank shall be borne by the Buyer.
- 9.8. The Buyer shall reimburse the Seller for all reasonable costs and expenses incurred in collecting overdue amounts, including legal fees, collection agency fees, court fees and enforcement costs.
- 9.9. Ownership of any intellectual property created during custom synthesis shall not pass to the Buyer unless expressly agreed in writing.
- 9.10. The Buyer shall not be entitled to withhold, set off or deduct any amount from payments due to the Seller unless the Buyer's claim has been finally established by a court of competent jurisdiction or expressly acknowledged by the Seller in writing.

## 10. Insolvency / Credit Risk

- 10.1. If the Seller reasonably determines that the Buyer's financial condition has materially deteriorated or that there is a significant risk of non-payment, the Seller may require advance payment, additional security, or suspend further deliveries until satisfactory assurances of payment are provided.

## 11. Cancellation Policy

- 11.1. If the Buyer cancels or postpones a confirmed order, in whole or in part, the Buyer shall be liable to pay 60% of the total value of the cancelled or postponed order.

## 12. Special Conditions for Custom Synthesis

- 12.1. The Seller reserves the right to revise the quoted price and/or delivery date based on preliminary synthesis results.

- 12.2. The Buyer may accept the changes or withdraw the order within seven (7) calendar days of notification.
- 12.3. Orders shall be deemed confirmed only upon full receipt of the agreed advance payment on the Seller's bank account, based on the relevant proforma invoice. The lead time specified in the offer shall commence on the date such payment is credited.
- 12.4. The Buyer acknowledges that custom synthesis may involve technical and scientific uncertainty. If the Seller determines that the synthesis cannot be successfully completed due to complexity, technical limitations, insufficient yield, quality issues or other feasibility constraints, the Seller may withdraw from the order and shall refund the advance payment in full. Unless otherwise required by mandatory applicable law, the Buyer shall not be entitled to any further claims, compensation, damages, penalties, lost profit or reimbursement of costs in connection with such unsuccessful or unfeasible synthesis.
- 12.5. In case of delays due to unavoidable technical issues, any compensation shall be limited to 0.8% per week of delay, calculated exclusively on the net value of the specific product(s) or part(s) of the order affected by the delay, and shall in no event exceed 10% of the net order value.
- 12.6. The Seller may terminate the contract if performance becomes impossible due to such technical issues. Any further claims are excluded.
- 12.7. Radiopharmaceutical prioritization  
In the event of unexpected and unavoidable technical difficulties affecting the production of radiopharmaceuticals or radiochemical, the Seller may reorganize production schedules and temporarily suspend manufacture of certain products in order to maintain supply of critical products.
- 12.8. Additional analysis / purification costs  
The costs of any repeated analyses requested by the Buyer after completion of synthesis and any additional purification requested by the Buyer shall be charged separately.
- 12.9. Shipping instructions and storage  
If the Buyer fails to provide complete shipping instructions within fourteen (14) calendar days after the Seller's notification of completion of the synthesis, the full purchase price shall become immediately due and payable. If an advance payment has been made, only the outstanding balance shall become due. Any storage after completion shall be subject to separate agreement on storage fee, conditions and duration. Unless otherwise agreed in writing, the Seller shall not guarantee that the material will maintain its original quality during storage, provided that the material is stored in accordance with the Seller's standard storage practices.
- 12.10. IP rights  
The synthesis route remains the intellectual property of the Seller unless otherwise agreed.
- 13. Safety Data Exchange Clause for Pharmaceuticals**
- 13.1. The Buyer shall promptly inform the Seller of any complaint or issue related to quality, safety, efficacy, or performance, including adverse events, misuse, or off-label use.
- 13.2. Reports shall be submitted via the Seller's reporting system or to: [gyogyszerbiztonsag@izotop.hu](mailto:gyogyszerbiztonsag@izotop.hu).
- 13.3. If a Pharmacovigilance Agreement exists, it shall prevail.
- 13.4. The Buyer shall report to the Seller any adverse event, serious adverse event, suspected adverse reaction, product quality complaint, medication error, falsified medicinal product, suspected lack of efficacy or any other information relevant to pharmacovigilance without undue delay and, where possible, no later than twenty-four (24) hours after becoming aware of such information.
- 14. Product Recall**
- 14.1. If the Seller reasonably determines that a recall, market withdrawal, field safety corrective action or similar corrective measure is required, the Buyer shall fully cooperate with the Seller and the competent authorities, including immediate cessation of distribution, identification of affected batches, notification of customers where required and return or destruction of Products in accordance with the Seller's written instructions.
- 15. Complaints**
- 15.1. Complaints regarding visible defects or quantity shortages must be submitted in writing, with supporting evidence, without delay and at the latest within fifteen (15) calendar days from receipt of the goods.
- 15.2. If the complaint is justified, the Seller shall, at its sole discretion:
- replace the goods,
  - remedy the defect,
  - refund the purchase price against return of the goods, or
  - grant an appropriate price reduction.
- 15.3. These remedies shall be the Buyer's sole and exclusive remedies and it is within the Seller's discretion to decide which of them to apply. Any further claims are excluded.
- 15.4. Hidden defects must be reported within the expiry period indicated on the Product or, if none is stated, within thirty (30) calendar days from receipt.
- 15.5. Where the unit of the product is activity, delivery shall be deemed compliant if within  $\pm 10\%$  of the ordered quantity in accordance with the European Pharmacopoeia.
- 15.6. The Buyer shall not use, process, alter or further distribute any Products that are the subject of a complaint unless expressly authorized by the Seller in writing. Any such use may result in forfeiture of the claim. The Buyer shall immediately quarantine the affected Products and prevent further distribution pending the Seller's written instructions.
- 15.7. The Buyer shall retain all relevant samples, packaging materials and supporting documentation relating to the alleged defect and shall make them available to the Seller in their original condition upon request.
- 15.8. The Buyer shall bear the burden of proving that the alleged defect existed at the time the risk passed to the Buyer.
- 16. Return Deliveries**
- 16.1. Returns are subject to prior written approval of the Seller.
- 17. Regulatory Changes**
- 17.1. If changes in applicable laws, regulations or regulatory authority requirements materially affect the manufacture, supply or distribution of the Products, the Seller may amend the applicable specifications, documentation or contractual requirements as reasonably necessary to ensure continued regulatory compliance.
- 18. Liability**
- 18.1. Products may be hazardous. The Seller shall not be liable for damages resulting from improper storage, handling, use, or disposal. After delivery and acceptance of the Products, the Buyer shall be solely responsible for ensuring that the Products are stored, handled and maintained in accordance with the applicable storage conditions, instructions and specifications provided by the Seller and/or required by applicable law. The Buyer shall keep proper, continuous and verifiable records evidencing compliance with such storage conditions, including, where relevant, temperature logs and other required storage data.
- 18.2. The Seller shall not accept any complaint, claim or liability relating to the quality, stability, performance or usability of the Products if the Buyer fails to demonstrate, by appropriate written records, that the prescribed storage conditions have been fully complied with after delivery and acceptance.

- 18.3. Any temperature excursion, storage deviation or transportation incident potentially affecting Product quality shall be documented by the Buyer and immediately reported to the Seller.
- 18.4. The Buyer is responsible for ensuring that all safety information is communicated to end users.
- 18.5. To the maximum extent permitted by applicable law, the Seller shall not be liable for any indirect, incidental, consequential, special or punitive damages, including loss of profit, loss of revenue, loss of business opportunity or loss of goodwill.
- 18.6. The Seller's aggregate liability arising out of or in connection with any contract shall in no event exceed the net purchase price of the Products giving rise to the claim.
- 18.7. Except as expressly set out herein, the Products are supplied "as is" and the Seller makes no representations or warranties, whether express, implied or statutory, including without limitation any warranty of merchantability, fitness for a particular purpose, non-infringement, or suitability for the Buyer's intended use. The Buyer assumes full responsibility for determining the suitability of the Products for its intended purposes.
- 18.8. The limitations and exclusions of liability set out herein shall apply regardless of the legal basis of the claim, whether arising in contract, tort (including negligence), statutory duty or otherwise.
- 18.9. The Buyer shall indemnify and hold harmless the Seller against any claims, losses, liabilities, damages, costs and expenses arising from the Buyer's handling, processing, use, resale, distribution or application of the Products, except to the extent caused by the Seller's gross negligence or willful misconduct.
- 18.10. The Products are intended for professional, industrial, research, diagnostic or pharmaceutical use only and are not intended for consumer use unless expressly stated otherwise by the Seller.
- 18.11. The Buyer shall ensure that all applicable handling, storage, transportation, radiation protection, pharmaceutical and safety regulations are complied with by its personnel, contractors, customers and end users.
- 18.12. The Buyer shall ensure that all radioactive Products are handled, transported, stored and disposed of exclusively by appropriately trained personnel in accordance with all applicable radiation protection legislation and license conditions.
- 18.13. Nothing in these General Conditions shall exclude or limit any liability that cannot be excluded or limited under applicable law.
- 19. Buyer's Regulatory Responsibility**
- 19.1. The Buyer shall be solely responsible for obtaining and maintaining all licenses, permits, authorizations and regulatory approvals required for the import, transport, storage, handling, use, resale or disposal of the Products in the country of destination.
- 19.2. The Seller shall not be liable for any losses, delays, costs or damages arising from the Buyer's failure to obtain or maintain such approvals.
- 19.3. Where the Products are medicinal products or active substances, the Buyer represents and warrants that it holds all licenses, authorizations and wholesale distribution permits required under applicable pharmaceutical legislation and that it shall comply with applicable Good Distribution Practice (GDP) requirements throughout storage, transportation and further distribution.
- 19.4. Counterfeit Medicines  
The Buyer shall immediately notify the Seller if it becomes aware of any suspected falsified medicinal product, product tampering, theft, diversion, counterfeiting or other incident affecting the integrity or traceability of the Products.
- 19.5. Traceability  
The Buyer shall maintain complete traceability records for all Products, including batch numbers, expiry dates, recipients and distribution records, for the period required under applicable pharmaceutical legislation.
- 20. Supplier Audits**
- 20.1. Where reasonably necessary and to the extent permitted by applicable law, the Buyer shall permit the Seller to conduct quality audits relating to the handling, storage and distribution of the Products, subject to reasonable prior notice and appropriate confidentiality obligations.
- 20.2. The Buyer shall reasonably cooperate with the Seller in connection with any inspection or investigation by a competent regulatory authority relating to the Products.
- 21. Re-export Prohibition, Export Control and Sanctions Compliance**
- 21.1. Re-export is not permitted without prior written consent of the Seller.
- 21.2. The Buyer shall comply with all applicable export control, sanctions, customs and foreign trade laws and regulations.
- 21.3. The Buyer shall provide, upon request, all information and end-user documentation reasonably required by the Seller to comply with applicable export control, sanctions and dual-use regulations. The Buyer shall not directly or indirectly export, re-export, transfer or otherwise make available the Products to any country, entity or person subject to applicable sanctions or export restrictions.
- 21.4. The Seller may suspend performance or terminate any order without liability if compliance with applicable export control or sanctions laws so requires.
- 22. Anti-Bribery and Compliance**
- 22.1. Each Party represents and warrants that it shall comply with all applicable anti-corruption, anti-bribery and anti-money laundering laws and regulations in connection with the performance of this Agreement.
- 22.2. Each Party shall maintain an effective compliance program reasonably designed to prevent violations of applicable anti-corruption, sanctions, export control and competition laws.
- 22.3. The Seller may terminate the Agreement with immediate effect upon becoming aware of any material breach of this clause.
- 23. Patent and IP Rights**
- 23.1. The Seller does not warrant that the manufacture, sale, importation, use or resale of the Products will be free from patent, trademark or other intellectual property claims in any jurisdiction.
- 23.2. The Buyer shall be responsible for determining whether the Products may be used, imported or commercialized in the intended territory without infringing third-party rights.
- 24. Confidentiality**
- 24.1. Each Party shall keep confidential all technical, scientific, commercial and business information received from the other Party that is designated as confidential or that reasonably should be understood to be confidential, except where disclosure is required by law or by a competent authority or is reasonably necessary for regulatory inspections, pharmacovigilance obligations, quality investigations, Product recalls or court proceedings.
- 25. Data Protection**
- 25.1. The Seller processes personal data in connection with quotations, orders, deliveries, invoicing, contractual performance, customer communication and the enforcement of legal rights in accordance with its Privacy Policy available on the Seller's official website.

- 25.2. Where personal data is processed for the purposes of safety reporting, quality complaints, adverse event reporting, product safety or pharmacovigilance, such processing shall be carried out in compliance with applicable pharmacovigilance and pharmaceutical laws, including the GDPR where applicable. Such processing may include special categories of personal data where necessary for compliance with legal obligations relating to medicinal Product safety, public health or pharmacovigilance.
- 25.3. The Buyer shall ensure that any personal data of its employees, representatives, customers, patients, end users or other third parties disclosed to the Seller is provided lawfully and that such persons have been duly informed about the disclosure and processing of their personal data.
- 25.4. Each Party shall implement appropriate technical and organizational measures to ensure a level of security appropriate to the risk in accordance with Article 32 GDPR or any equivalent applicable data protection legislation.

## **26. Force Majeure**

- 26.1. The Seller shall not be liable for any failure or delay caused by circumstances beyond its reasonable control, including but not limited to natural disasters, war, pandemic, governmental actions, energy or raw material shortages (e.g. radionuclides) or disruptions in the supply chain. Such events entitle the Seller to suspend performance or terminate the contract, in whole or in part, without liability.
- 26.2. Force Majeure shall include, without limitation, economic sanctions, export control restrictions, embargoes, governmental measures, and any restrictions imposed by the United Nations, the European Union, the United States or other competent authorities.

## **27. Disputes**

- 27.1. The Parties shall attempt to resolve disputes amicably.
- 27.2. Applicable law: Hungarian substantive law.
- 27.3. Any dispute arising out of or in connection with these General Conditions shall be finally settled by arbitration under the Rules of Procedure of the Arbitration Court attached to the Hungarian Chamber of Commerce and Industry (HCCI). The seat of arbitration shall be Budapest, Hungary. The language of the arbitration shall be English.
- 27.4. Notwithstanding the foregoing, the Seller shall be entitled, at its sole discretion, to bring actions for the recovery of monetary claims, debt collection, interim or conservatory measures or enforcement before any court having jurisdiction over the Buyer or its assets.

## **28. Severability**

- 28.1. If any provision in whole or in part of these General Conditions is held to be invalid under the laws of any jurisdiction, illegal or unenforceable, the remaining provisions shall remain in full force and effect. The Parties shall replace the invalid provision with a valid provision that most closely reflects the original economic intent.
- 28.2. To the extent permitted by applicable law, any invalid, illegal or unenforceable provision shall be deemed replaced by a valid and enforceable provision that most closely reflects the original commercial purpose and economic intent of the Parties. Where such replacement is not possible, the relevant mandatory provisions of Hungarian substantive law shall apply to the extent necessary to fill the gap created by such invalidity, illegality or unenforceability.

## **29. Entire Agreement**

- 29.1. These General Conditions, together with any quotation, order acknowledgement and written agreement between the Parties, constitute the entire agreement relating to the sale of the Products and supersede all prior discussions, representations and understandings relating thereto.