

## **General Terms and Conditions – Analytisches Zentrum Biopharm GmbH Berlin**

### **1. Scope of validity/General information**

1.1 These General Terms and Conditions ("GTC") shall apply to all the legal relationships of the Analytisches Zentrum Biopharm GmbH Berlin ("we", "us/our" or "AZ-BIOPHARM"). They apply to all transactions within the entire business relationship and to follow-up orders in ongoing business relationships.

1.2 AZ-BIOPHARM shall not recognize any terms and conditions of business of the customer that conflict with, deviate from or supplement these GTC unless AZ-BIOPHARM expressly agrees to their validity in writing. This requirement for consent and these GTC shall also apply to orders that are placed verbally, also if AZ-BIOPHARM completes an order without reservation in the knowledge of contrary or deviating conditions on the part of the customer (for example, in the case of orders which arise through the transfer of samples).

1.3 Individual agreements with the customer take precedence over these GTC. All agreements made between us and the customer for the purpose of completing a transaction must be recorded in writing. The same applies to legally-relevant declarations and notifications (for example, the setting of deadlines, declarations of withdrawal, notices of termination, notifications of defects) made by the customer after the conclusion of the contract.

1.4 These GTC shall only apply, however, if the customer is an entrepreneur within the meaning of Section 14 BGB (German Civil Code), a legal entity under public law, or a special fund under public law.

### **2. Conclusion and implementation of the contract**

2.1 Unless otherwise stated in the specific offer, our offers are always subject to change and are non-binding. Purchase orders placed by the customer shall be considered to be a binding contractual offer and may be accepted within a period of two weeks, unless a different binding period has been agreed in writing. However, orders shall also be considered to have been accepted when we commence their completion.

2.2 Orders shall be completed by AZ-BIOPHARM impartially, carefully and professionally in accordance with the normal industry standards, applicable laws, professional standards and our quality management system. Upon the request of the customer, we will inform the customer about the respective official permits at the time of the conclusion of the contract, and refer to the information provided on our website for the corresponding current permits.

2.3 Unless agreed otherwise in writing, we reserve the right to also carry out the services by engaging professionally qualified third parties – in particular, experts working for us – or to engage subcontractors. This shall only take place with the prior written consent of the principal.

2.4 Changes to services requested by the customer following the commissioning must not affect the validity of the results. Changes to services shall be stipulated in a written additional agreement before they are provided; the additional remuneration and any changes to the time schedule shall also be set out in the additional agreement. Insofar as it is apparent during an analysis that this will not lead to a usable result due to the nature of the sample or the nature of a test specimen according to the prescribed or agreed test procedures, AZ-BIOPHARM shall make suggestions as to how the analysis should be continued. In this case, the customer shall bear the costs of the resulting additional expenditure, unless agreed otherwise. Further examinations associated with costs will only be carried out after written commissioning by the principal.

2.5 For the final evaluation of test reports and the clarification in tenders, the decision-making rules are defined as follows: a. Application of statutory requirements (e.g. limit values): depending on the order and the analytics, the decisions / evaluations are based on the statutory requirements. The normative specifications are noted on the test report and, if clearly definable before the analysis, on the offer. Consideration of measurement uncertainties in assessments:

- GB Bioanalytics: The final results are calculated in the LIMS using the validated procedures stored there.
- GB Pharmaceutical Analytics: When considering the conformity of given specification limits, roundings are taken into account in accordance with the specifications in the standards, which are stored in the test specifications.

### **3. Samples, test specimens, materials: Obligations and ownership**

3.1 Samples, materials and test specimens must be in a condition that allows the services that are ordered to be carried out without any problems.

3.2 The customer shall be obliged to notify AZ-BIOPHARM of all known hazard- and handling instructions associated with the samples, materials and test specimens. Any health or safety concerns arising from the samples, materials and test specimens shall be indicated in writing. This includes, in particular, concerns regarding known or suspected toxic substances or other contamination and the suspected degree of contamination, as well as risks to property and the other legal assets of AZ-BIOPHARM as well as its employees and other representatives. If, on the basis of an incoming goods inspection, it turns out that it is impossible for AZ-BIOPHARM to carry out the agreed service due to the burden, AZ-BIOPHARM shall be entitled to withdraw from the contract or may interrupt the performance of the order. In this case, the customer shall bear the costs incurred by AZ-BIOPHARM up to this point in time.

3.3 AZ-BIOPHARM shall be entitled to dispose of or destroy the samples for the preparation and performance of the analysis and to dispose of and destroy the specific samples, materials or test specimens immediately after the analysis has been carried out or the work has been completed, unless the storage is required by law or has been agreed in writing. If a specific retention period has been agreed, the agent shall be entitled to remove or destroy the goods after the expiry of this period, subject to prior written notice. If the customer requests the goods to be returned or sent back, AZ-BIOPHARM shall arrange for the goods to be returned at the customer's expense and risk.

3.4 In all other respects, the sending of samples, materials and test specimens or any other logistical measures by the customer shall be at the customer's risk and expense and shall be carried out by the customer itself. Insofar as AZ-BIOPHARM provides assistance in this respect, AZ-BIOPHARM shall act on behalf of the customer.

### **4. Time limits and deadlines, obligations to cooperate**

4.1 Dates and deadlines are estimates and shall not constitute an obligation; AZ-BIOPHARM shall, however, make reasonable commercial efforts to comply with the dates and deadlines. Dates and deadlines are otherwise only binding if expressly agreed in writing in the individual case.

4.2 The customer shall ensure that AZ-BIOPHARM is provided with all information and documents required for the performance of the services free of charge and in good time. The time limit for the completion shall only commence on the date of our acceptance of the order, but not before complete clarification of all details of the completion, insofar as these are necessary for the completion of the order (including test methods, specifications, reference substances, materials to be provided, etc.).

4.3 The agreed period for the completion of the order shall be extended - without prejudice to our rights arising from default on the part of the customer and any statutory right of withdrawal - by the period by which the customer is in default with its contractual (cooperation) obligations or payment obligations. The same shall apply if a date for the completion has been agreed.

### **5. Prices and terms of payment**

5.1 The prices agreed in the orders shall apply to our services. Unless agreed otherwise in writing, all prices are exclusive of shipping; costs for rush orders and for special packaging are to be paid separately. Our prices are exclusive of the statutory rate of value added tax.

5.2 Unless agreed otherwise, the payment shall be made without deductions within 14 days of receipt of the invoice and the delivery of the work results.

5.3 All our claims shall become due immediately if the terms of payment are not complied with or should we become aware of circumstances which are likely to reduce the creditworthiness of the customer. AZ-BIOPHARM shall also be entitled to withhold services from other orders - to a reasonable extent and scope. Furthermore, we are also entitled to carry out outstanding services only against advance payment or to demand appropriate securities and, if the customer ultimately refuses to fulfil the contract or to provide securities or has not performed the service in return or provided securities after setting a deadline, to withdraw from the contract. The statutory provisions on the dispensability of setting a deadline and the assertion of claims for damages shall remain unaffected.

5.4 The customer shall only be entitled to offsetting rights if its counterclaims have been legally established, are undisputed or have been acknowledged by AZ-BIOPHARM. Any rights of the customer to charge back or to withhold payment shall be excluded unless they are based on the same contractual relationship. In the event of service defects, however, the statutory counter rights of the customer shall remain unaffected.

5.5 Irrespective of the rights set out in these GTC, AZ-BIOPHARM shall retain its statutory rights on account of the customer's default in payment and due date for payment.

## **6. Performance defects and liability**

6.1 The services to be rendered by AZ-BIOPHARM shall be carried out according to the current state of the art and by applying a standard of care that is commercially reasonable and customary in the industry.

6.2 The services of AZ-BIOPHARM shall be considered to have been accepted if the customer has not declined their acceptance within 10 working days of receipt of the expert opinions, analyses, reports or other services provided, with reference to a defect that is not merely insignificant and actually exists - or is at least obvious from an objective point of view. Under all circumstances, the customer shall be obliged to verify the validity of the results, interpretations, estimates and conclusions communicated by AZ-BIOPHARM with reasonable care at its own risk, insofar as the customer wishes to rely on these in matters of significance. The customer shall be obliged to inform AZ-BIOPHARM immediately if the services supplied are clearly defective.

6.3 In the event of defects, we shall decide at our own discretion as to whether we shall provide subsequent performance in the form of the rectification of the defect or the renewed completion of the service. Claims for defects shall become statute-barred within one year of the statutory commencement of the limitation period; this shall not apply in the event of the fraudulent concealing of a defect.

6.4 Unless expressly agreed otherwise in writing, a contractual relationship shall only exist between AZ-BIOPHARM and the customer, and no contract shall be concluded in favour of third parties or with protective effect for third parties.

6.5 The customer undertakes to indemnify AZ-BIOPHARM of all claims by third parties that are based on a breach of duty and/or a fault on the part of the customer.

6.6 Unless stated otherwise in these GTC, AZ-BIOPHARM shall be liable in accordance with the relevant statutory provisions in the event of a breach of contractual and non-contractual obligations. AZ-BIOPHARM shall be liable for damages - irrespective of their legal grounds - in the event of intent and gross negligence. In the case of simple negligence, AZ-BIOPHARM shall only be liable for damages resulting from the infringement of an essential contractual obligation (obligation whose proper fulfilment makes the proper completion of the contract possible in the first place and on whose fulfilment the contractual partner may regularly rely); in this case, however, the liability of AZ-BIOPHARM shall be limited to compensation for foreseeable, typically occurring damage.

6.7 The liability of AZ-BIOPHARM for damages caused by delay shall be limited to a maximum of 25% of the net order value, except in cases of intent or gross negligence.

6.8 The above exclusions and limitations of liability shall apply to the same extent in favour of the bodies, legal representatives, employees and other vicarious agents of AZ-BIOPHARM. They shall not apply insofar as AZ-BIOPHARM has fraudulently concealed a defect or has provided an express guarantee. The same applies to damages arising from injury to life, limb and health as well as claims under the Product Liability Act.

6.9 Should the customer exercise its statutory right of termination pursuant to Section 648 of the German Civil Code (BGB) (in the case of work performance), in deviation from the statutory presumption, AZ-BIOPHARM shall be entitled to 10 percent of the agreed remuneration attributable to the part of the work performance that has not yet been performed.

## **7. Confidentiality and Data Protection**

7.1 The parties shall treat as confidential all business and operational matters of the other party of which they become aware or which become known to them in connection with the business relationship and which are marked as confidential, or where confidentiality arises from the nature of the information, in particular, business secrets.

7.2 AZ-BIOPHARM shall be obliged to make commercially reasonable efforts to treat all work results as confidential. This shall not apply if claims for payment for work that has been provided have to be proven. We are furthermore authorised to disclose, pass on or make our own use of the knowledge gained in the course of our activities if we are obliged to do so by law, or if the customer expressly absolves us from the duty of confidentiality in writing. Furthermore, we are authorized to use, publish and subject to independent scientific evaluation the results of investigations within the scope of activities rendered in an anonymous form for scientific or statistical purposes in compliance with data protection laws, provided that no legitimate interests of the customer that are known to us are opposed to this, and unless agreed otherwise.

7.3 The customer may only use the work results (test, certification, analysis results) for the agreed purposes and only make them available to third parties who have been previously determined in writing. The customer shall be entitled to disclose the test results if the customer is obliged to disclose them by law, by the authorities or by a court of law, about which the customer shall inform AZ-BIOPHARM.

7.4 During the fulfilment of the order, AZ-BIOPHARM shall process personal data to the extent that is necessary. This includes, in particular, the names and business contact details of the customer's contact persons. This data is processed exclusively for the purpose of fulfilling orders, invoicing and transmitting the analysis results. For more information, refer to the privacy policy on our website.

## **8. Place of performance, choice of law and place of jurisdiction**

8.1 The place of performance for the obligations arising from the contractual relationship is the registered office of our branch (Berlin), unless otherwise specified.

8.2 These GTC as well as the contracts concluded within the scope of these GTC are subject to German law. The United Nations Convention on Contracts for the International Sale of Goods dating from 11th April 1980 (UN Sales Law, CISG) shall not apply.

8.3 The exclusive place of jurisdiction is Berlin, insofar as the customer is a merchant, a legal entity under public law or a special fund under public law. This also applies if the domicile or usual place of residence of the customer is unknown, is located abroad or is relocated there.

8.4 AZ-BIOPHARM shall also be entitled to instigate legal action at the general place of jurisdiction of the customer.

8.5 If the customer has its registered office outside the European Economic Area, the following shall apply in deviation from Sections 8.3 and 8.4: All disputes which arise from the contractual relationship between the customer and AZ-BIOPHARM shall ultimately be resolved by

an Arbitrator according to the Arbitration Rules of the German Arbitration Institute (DIS), without recourse to the ordinary courts of law. The place of arbitration shall be Berlin. The language of the proceedings shall be German unless the parties agree to another language.