

## TentaConsult Regulatory Services GmbH Fraunhoferstr. 9, 82152 Planegg/Martinsried

### 1 SCOPE OF APPLICATION

1.1 Our General Terms and Conditions of Business (*Allgemeine Geschäftsbedingungen, AGB*) shall apply to all contracts concluded between TENTACONSULT REGULATORY SERVICES GmbH (hereinafter "TENTACONSULT REGULATORY SERVICES") and companies as defined in § 14 German Civil Code (*Bürgerliches Gesetzbuch, BGB*), legal entity under public special assets (hereinafter referred to as the "Customer").

1.2 These General Terms and Conditions shall apply exclusively. Conflicting or deviating conditions or regulations have to be agreed in writing (*Textform*) to be legally valid and have to be signed by a person authorized therefor. Persons authorized within the meaning of these General Terms and Conditions are only managing directors, division managers and project managers of TENTACONSULT REGULATORY SERVICES. Agreements made with other employees, in particular by telephone, shall only become valid if confirmed in writing (*Textform*) by one of the above-mentioned authorized persons.

1.3 The General Terms and Conditions of the Customer shall not apply even if TENTACONSULT REGULATORY SERVICES fails to expressly object to their application in the individual case. Even if TENTACONSULT REGULATORY SERVICES makes reference to a document which contains the General Terms and Conditions of the Customer or a third party or makes reference thereto, this shall not be deemed as agreement of TENTACONSULT REGULATORY SERVICES with the applicability of those terms and conditions.

### 2. PLACEMENT OF ORDERS AND CONTRACT CONTENT

2.1 In principle, orders shall be placed in writing. In case of an order placement made only verbally, transmission errors as well as any misunderstandings shall be for the account of the Customer. As far as the order is confirmed by TENTACONSULT REGULATORY SERVICES in writing (*Textform*), the contract shall be deemed to be concluded upon receipt of said order confirmation by the Customer. In case of doubts, the scope and content of the contract are as set forth in the order confirmation. Amendments of the contractually agreed scope of performance must be agreed in writing and can be made only with a person accordingly authorized by TENTACONSULT REGULATORY SERVICES.

2.2 Deadlines for performing orders are non-binding unless expressly agreed to be binding in writing

(*Textform*). TENTACONSULT REGULATORY SERVICES shall be liable for failure to meet deadlines according to the statutory provisions, insofar as the default in performance is based on an intentional or negligent breach of contract for which TENTACONSULT REGULATORY SERVICES is responsible; TENTACONSULT REGULATORY SERVICES is responsible for faults of its representatives or vicarious agents.

2.3 TENTACONSULT REGULATORY SERVICES owes the performance of services, not the success with respect to the acceptance of authorities or in regulatory proceedings.

2.4. In an event of force majeure, such as labor disputes, unrest, public authority measures and similar circumstances, which are beyond TENTACONSULT REGULATORY SERVICES's control, TENTACONSULT REGULATORY SERVICES shall be released from its obligations to perform its contractual duties for the duration of the disruption. This shall also apply, if these circumstances occur at TENTACONSULT REGULATORY SERVICES's subcontractors or if these events occur at a point in time at which TENTACONSULT REGULATORY SERVICES is already in default. TENTACONSULT REGULATORY SERVICES shall notify the Customer of the start and end of such inability to perform.

### 3. DELIVERY

Documents delivered within Germany shall be free of packaging, postage and shipping costs. The right to make partial deliveries is reserved. The costs of goods delivered within Germany and abroad shall always be charged to the Customer. In case of deliveries abroad which are subject to VAT, the Customer shall provide all documents which are required by TENTACONSULT REGULATORY SERVICES for deduction of input tax.

### 4. PRICES, PAYMENT DUE DATE, DEFAULT

4.1 The remuneration for all services shall be agreed upon at the conclusion of the contract. If the parties do not agree on a price different from the price defined in the offer, the price in the offer shall be valid. In accordance with § 271 BGB, the invoice amount is to be paid immediately unless a payment date has been agreed within the contract or has been specified by TENTACONSULT REGULATORY SERVICES on the invoice. The invoice amount is payable net; no deduction shall be granted. The stipulated prices are net of VAT.

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4.2 The Customer may only set off counter-claims or assert a right of retention to the extent that the counter-claims are uncontested, or have been established by a court, or if the claim of TENTACONSULT REGULATORY SERVICES is in a relationship of mutuality with the counter-claim by the Customer.

4.3 TENTACONSULT REGULATORY SERVICES reserves the right to process an order by means of payment of cash on delivery, partial advance payment or advance payment. As applicable, the Customer will be informed accordingly in advance.

4.4 In cases of default of payment by the Customer, TENTACONSULT REGULATORY SERVICES shall be entitled to charge interest for late payment from the due date at a rate of 5 (five) percentage points above the base interest rate. If the claim for late payments is towards an entrepreneur, TENTACONSULT REGULATORY SERVICES shall charge interest for late payment from the due date at a rate of 9 (nine) percentage points above the base interest rate. The claim for a higher rate of interest and additional damages in case of default remains unaffected.

4.5 If the Customer fails to pay an agreed installment when due, either in whole or in part, TENTACONSULT REGULATORY SERVICES shall have the right to demand either immediate payment of the full amount owed or to rescind the contract following the futile lapse of a payment extension period. In this case, the Customer shall reimburse TENTACONSULT REGULATORY SERVICES for the damage accruing therefrom.

### 5. DUTY OF COOPERATION

The Customer transmits information, documents, literature or data of the Customer, as far as needed for the services to be provided, at his costs.

### 6. DATA PROTECTION

The personal data of the client collected in connection with the performance of the contract (in particular the first names and surnames of authorized representatives, e-mail addresses and other contact data of employees) will be processed in compliance with data protection regulations

### 7. WARRANTY CLAIMS

7.1 TENTACONSULT REGULATORY SERVICES shall be liable for the defectiveness of delivered data, data carriers or other services (advice, information) and shall fulfil such liability by repeating the defective

delivery or service free of charge. Should the defects not be remedied or TENTACONSULT REGULATORY SERVICES is not prepared or in a position to render remedy of the defect or replacement delivery or should such be delayed beyond a reasonable extension period for reasons for which TENTACONSULT REGULATORY SERVICES is not responsible, the Customer shall be entitled to rescind the contract or to demand reduction of the purchase price. For damage claims and reimbursement of wasted expenses/efforts (*Vergebliche Aufwendungen*) due to a defect, § 8 Liability hereof shall apply.

7.2. The Customer has to notify TENTACONSULT REGULATORY SERVICES in writing of any defects within 30 days after sending the work results; otherwise any claims because of such a defect are excluded.

7.3 The Customer's claims for defects shall be time-barred after expiration of 1 (one) year after the delivery or complete and final performance of the service by TENTACONSULT REGULATORY SERVICES. The statutory period of limitation shall apply instead of the 1 (one)-year period in the following cases: i) in the case of liability caused by intentional misconduct, ii) in cases of fraudulent non-disclosure of a defect, iii) for claims due to damage arising out of death, injury to body or health which is based on a negligent breach of obligation by TENTACONSULT REGULATORY SERVICES, iv) for claims due to damage arising out of death, injury to body or health which is based on an intentional or negligent breach of obligation of a legal representative or vicarious agent of TENTACONSULT REGULATORY SERVICES, v) for other claims which are based on a grossly negligent breach of obligation of TENTACONSULT REGULATORY SERVICES or an intentional or grossly negligent breach of obligation of a legal representative or a vicarious agent of TENTACONSULT REGULATORY SERVICES.

### 8. LIABILITY

8.1 Liability on the part of TENTACONSULT REGULATORY SERVICES, regardless of the legal grounds therefor, is limited according to the following sub-clauses as far as fault (*Verschulden*) is relevant in the respective case (including the fault of company organs, legal representatives, employees or other vicarious agents).

8.2 TENTACONSULT REGULATORY SERVICES shall be liable in cases of slight negligence only for breach of material contractual obligations. A material

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contractual obligation includes without limitation the delivery free from defects and/or service which should make the use of the contractual results possible for the Customer according to the contract. In such cases, liability is limited to the foreseeable damages typical for such contracts.

8.3 Indirect damage and consequential damage caused by defects of the work results shall only be reimbursable as far as such damage could typically be expected despite proper use.

8.4 The limitations of this clause shall not apply for liability on the part of TENTACONSULT REGULATORY SERVICES insofar as a limitation of liability is mandatorily precluded by law. This relates especially to the liability for willful misconduct and gross negligence and for the injury to life, body and health.

### 9. TRANSPORT DAMAGE

Should the Customer detect damage to the packaging (transport damage), the Customer shall have the damage attested by the transport carrier upon acceptance of the shipment. Transport damage which is first determined after unpacking the goods must be notified to and received by TENTACONSULT REGULATORY SERVICES within 3 (three) business days.

### 10. RIGHTS TO WORK RESULTS/PROTECTION OF WORK RESULTS

10.1 The Customer shall be the owner of all rights to the work results. Work results within the meaning of these General Terms and Conditions are reports, expert opinions and other documents which the Customer receives within the framework of the contract. This shall not apply to results made only on the occasion of the performance under the contract without any connection concerning the content of the contract and to results which are made or could arise independently from the corresponding project and without using the Confidential Information of the Customer.

10.2 The know-how which TENTACONSULT REGULATORY SERVICES uses or gains during the work remains the property of TENTACONSULT REGULATORY SERVICES. Insofar as this know-how is part of the contract, the Customer shall receive a limited, non-exclusive right to use such know-how according to the contract. TENTACONSULT REGULATORY SERVICES reserves the right to freely use its own know-how including, but not limited to,

to fulfil contracts of other customers and/or publications.

10.3 The Customer shall use the work results prepared by TENTACONSULT REGULATORY SERVICES within the framework of the analyses only for its own purposes and the purposes described in the respective individual contract. Within this framework, reproduction and transfer to third parties (e.g. regulatory authorities) shall be permitted. Any improper reproduction and/or transfer is prohibited and shall only be permitted upon prior consent of TENTACONSULT REGULATORY SERVICES in writing (*Textform*). In case the Customer is a part of a group of subordinated affiliates or parallel affiliated companies, transfer to the group companies shall require the express consent of TENTACONSULT REGULATORY SERVICES (prohibition of sub-licensing).

### 11. CONFIDENTIALITY

TENTACONSULT REGULATORY SERVICES and the Customer agree to keep information they receive in connection with the referring work order, business and trade secrets ("information") secret and confidential and neither to publish nor to make work results accessible to third parties. Furthermore, TENTACONSULT REGULATORY SERVICES agrees to keep the work results secret and confidential. Insofar as employees, affiliated companies and/or third parties must receive information pursuant to the contract, the party affected is allowed to forward the information to them, if they are obliged to keep the information secret and confidential for their part.

### 12. RETENTION OF TITLE TO OWNERSHIP, COPYRIGHT

12.1 TENTACONSULT REGULATORY SERVICES retains the title to ownership (*Eigentumsvorbehalt*) including, but not limited to, all copyrights of the delivered items (documents, data and data carriers) until receipt of the agreed remuneration in total. The Customer is obligated to notify TENTACONSULT REGULATORY SERVICES of every change of its registered office as long as accounts receivable are outstanding due to delivered documents or data or documents or data have not yet been delivered.

12.2 TENTACONSULT REGULATORY SERVICES reserves the copyright to documents and dossiers until full payment as agreed. TENTACONSULT REGULATORY SERVICES reserves the copyright to reports and professional statements without limitation; any other use than agreed needs the prior written confirmation of TENTACONSULT REGULATORY SERVICES.

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#### **13. TERMINATION**

Either party may terminate the services at any time within four (4) weeks in writing. If the Customer terminates the contract, the Customer shall reimburse TENTACONSULT REGULATORY SERVICES for all actually accrued costs (in particular, but not limited to, personnel, material, travel costs) and expenses up to the effective date of termination. In addition, in the case of a termination by the Customer, TENTACONSULT REGULATORY SERVICES is entitled to receive a percentage share of the agreed fee. This share shall be calculated by the actually elapsed development time in relation to the time which has been taken into consideration for the entire contract. In this case, the Customer is not entitled to receive the documentation related to the concluded sub-sections or partial results of the process development. If TENTACONSULT REGULATORY SERVICES terminates the contract, the Customer shall have the right to receive the documentation of such part of results up to this date; however, the Customer has to reimburse TENTACONSULT REGULATORY SERVICES for the accrued work hours, as well as the full costs (including personnel, material and travel costs) as well as expenses until the effective date of termination.

#### **14. TERMINATION FOR GOOD CAUSE**

Should it be determined during a project that achieving the aimed objective has become impossible for factual, legal or commercial reasons, TENTACONSULT REGULATORY SERVICES shall be entitled to termination for good cause, whereby TENTACONSULT REGULATORY SERVICES shall be entitled, in addition to receipt of payment of accrued costs (especially personnel, material and travel costs) as well as expenses, to a percentage share of the agreed fee. This share shall be calculated in accordance with Clause 13 of these General Terms and Conditions. In this case, the Customer shall be entitled to receive the documentation of the previous sub-sections and partial results.

#### **15. SEVERABILITY**

If one provision or several provisions of these Terms and Conditions become(s) invalid, void or unenforceable or prove(s) to be incomplete, the rest of the contract shall remain valid. The parties will – if necessary by adequate form – replace the invalid, void or unenforceable provision(s) which come(s) as close to the commercial purpose agreed to by the parties as possible.

#### **16. APPLICABLE LAW, PLACE OF PERFORMANCE, JURISDICTION**

These General Terms and Conditions and the contract shall be governed by German law without regard to its conflict-of-law provisions which would submit these General Terms and Conditions and the contract to other than German law. The rules of the UN Convention on the International Sale of Goods (CISG) (Vienna Convention) shall not apply. Place of performance is the registered office of TENTACONSULT REGULATORY SERVICES. If the Customer is a merchant, jurisdiction is in Munich (Bavaria).