

GENERAL TERMS AND CONDITIONS OF DELIVERY

Article 1 - Definitions and Applicability

- In these General Terms and Conditions of Delivery ("TERMS") the following is defined as:
 - CONSULTANT: Medtech Compliance Consult B.V.
 - CLIENT: Natural or legal person with whom CONSULTANT concludes an ORDER.
 - OFFER: Non-binding price indication and/or description of SERVICES to be delivered by CONSULTANT to fulfill a need of a potential CLIENT.
 - ORDER: A mutually confirmed agreement between CONSULTANT and CLIENT about a SERVICE to be rendered.
 - SERVICE: Any and all work, research, written documentation, other materials or (electronic) files produced, as well as results achieved by the CONSULTANT as part of an ORDER.
 - PARTY: Either CLIENT or CONSULTANT, collectively called PARTIES.
- These TERMS govern all ORDERS and apply to any relevant and prior acts or legal acts by the CONSULTANT and the CLIENT. Deviations of these TERMS are only valid if and in so far as these were explicitly confirmed by the CONSULTANT in writing with reference to the ORDER.
- In the event of any conflict the specific terms and conditions that are included in the ORDER prevail over these TERMS.
- The applicability of CLIENTS general terms and conditions, by whatever name, is explicitly rejected by CONSULTANT.

Article 2 - Offer and order confirmation

- OFFERS are not binding to CONSULTANT and can only be considered as an invitation to conclude on an ORDER.
- OFFERS remain valid for a period of 30 days, unless explicitly stated otherwise.
- Rates in OFFERS are excluding VAT, and any other government levies, unless explicitly stated otherwise.
- An ORDER is concluded only when an ORDER that is confirmed by the CLIENT is accepted by CONSULTANT through a order confirmation in writing, by email, or by signing any other document, or when CONSULTANT started the performance of the SERVICE as described in the OFFER.
- Number of days or hours listed in the ORDER to provide the agreed SERVICES as well as listed expenses are estimates and may deviate from the actual days, hours and expenses invoiced unless explicitly stated otherwise.
- Any additional oral ORDERS, alterations and stipulations that are not covered by the OFFER shall only be binding for CONSULTANT after written confirmation by CONSULTANT.
- The CLIENT cannot derive any rights for future ORDERS from OFFERS made nor from previously concluded ORDERS.

Article 3 - Planning and execution of the order

- The planning of the ORDER shall take place in collaboration with the CLIENT. The actual time will only be reserved by CONSULTANT after the ORDER is concluded and the planning is laid down in writing. CONSULTANT will adhere to agreed milestones dates as much as possible, but these milestones are in no event binding final deadlines.
- Upon exceeding agreed milestone dates the CLIENT is not entitled to compensation of damages.
- The CLIENT is solely responsible to do all and anything that is reasonably required or desirable to facilitate timely and correct execution of the ORDER by CONSULTANT, in particular by timely delivery of complete, valid and clear data or materials and by giving CONSULTANT access to people, locations, and areas to which CONSULTANT needs to have access in order to complete the ORDER correctly and in time.
- If the execution of the ORDER requires involvement of any third party, CLIENT will be informed on forehand, if possible. Whenever a third party is involved, CONSULTANT will observe due care.
- CONSULTANT shall perform the ORDER to the best of his knowledge and abilities, in accordance with the requirements of professional skill.
- The CLIENT shall be available for consultation at agreed times in respect of the planning and progress of the work.

Article 4 - Fees and payments

- Rates and expenses listed in the ORDER, order confirmations, or other written documents of CONSULTANT are exclusive of V.A.T. and any other government levies, unless expressly stated otherwise.
- The CLIENT is entitled to request CONSULTANT evidence of expenses invoiced and hours spent per SERVICE.
- With respect to claims denominated in foreign currency against debtors located outside Belgium, CONSULTANT will not be liable for any exchange differences, conversion differences and/or transfer problems.
- Invoices issued by CONSULTANT must be paid by the CLIENT within thirty days of the invoice date.
- All payments must be made without any deduction or set-off and without the CLIENT blocking its accounts by attachment or otherwise.
- If the CLIENT fails to pay the outstanding amounts within the term referred to in article 4, sub-clause 4, the CLIENT will be in default by operation of law and without notice from CONSULTANT, being required to pay a default interest of 6% per month, or the rate equal to the statutory (commercial) interest if the latter is higher, on the entire amount outstanding.
- In the event of debt collection all judicial and extra judicial costs incurred by CONSULTANT will be at the CLIENT's expense. This amount will in no event be lower than 20% of the total amount due and payable.
- CONSULTANT, at its sole discretion, determines against which outstanding amount the payment by the CLIENT will be applied first.

Article 5 – Complaints

- The CLIENT is obliged to immediately check whether the rendered SERVICES are in conformity with the ORDER. In the event the CLIENT believes the rendered SERVICES do not comply with the ORDER, the CLIENT shall inform CONSULTANT as soon as possible, and in all instances within eight days of rendering of the SERVICES, or of the time when it was reasonably possible to determine non-conformity, at the risk of forfeiting all relevant claims.
- In any case, complaints must be reported within three months after the rendering of the SERVICES, at the risk of forfeiting all relevant claims.

Article 6 - Copyright and Confidentiality

- All intellectual property rights, including copyrights, related to SERVICES provided to the CLIENT belong to CONSULTANT and shall only be transferred to the CLIENT after all invoices are fully paid. Multiplication will be allowed for internal use. This does not apply to phrases containing facts of general knowledge.
- The CLIENT is not allowed to publish and/or disclose and/or make public parts of the reports and other written documents prepared by CONSULTANT without written consent of CONSULTANT. This article also applies in the event the intellectual property rights are transferred to the CLIENT under the conditions of article 6.1. In the event of breach of the ban set out in this Article 6, the CLIENT will forfeit a penalty of 100% of the total price as mentioned in the ORDER (including variations in the amount of work) payable to CONSULTANT for each breach, without prejudice to CONSULTANT 's right to claim payment of the damage incurred or to invoke any other right(s).
- PARTIES are obliged to observe secrecy with regard to all confidential information that they obtain from each other or from another source within the framework of the ORDER. Information is regarded as confidential if the other PARTY has identified it as such or if this follows from the nature of the information.
- If a legal stipulation or judicial decision forces CONSULTANT to provide confidential information to third parties appointed by law or by a competent court, and CONSULTANT cannot claim exemption on the basis of any statutory legislation of legal provision acknowledged or allowed by court, then CONSULTANT shall not be obliged to pay damages or remedies and the other PARTY shall not be entitled to terminate the ORDER because of any damage caused by disclosure.

Article 7 - Force Majeure

- If any PARTY is unable to comply with its obligations towards each other within the agreed timeframe due to force majeure, the timeframe will be extended. Force majeure includes at least any circumstance that is independent on the will of the PARTY, including but not limited to, natural disasters, shortage of materials, company and/ or equipment breakdowns, strikes, measures taken by a government, problems with power supply, and faults by third parties engaged by CONSULTANT.

2. PARTIES may suspend the obligations arising from the ORDER for the duration of the force majeure. If the duration extends beyond two months, either PARTY is entitled to terminate the ORDER, without the obligation to pay damages to the other PARTY.
3. Insofar as CONSULTANT had fulfilled part of his obligations arising from the ORDER at the time when force majeure commenced, or shall be able to do so, and the part (to be) fulfilled has an independent value, then CONSULTANT is entitled to invoice the part that has already been fulfilled or shall be fulfilled. CLIENT is obliged to pay such an invoice as if it were a separate ORDER.

Article 8 - Liability and Indemnity

1. CONSULTANT will perform its SERVICES to its best knowledge but does not take on an obligation of result. For the avoidance of doubt the CLIENT is solely responsible for designing, development, classification, registration and marketing of its products.
2. CONSULTANT is not liable for any indirect damages suffered either by the CLIENT or third parties.
3. CONSULTANT is not liable for patient or user damages or harm in the medical, paramedical or pharmaceutical sector that may directly or indirectly be a consequence of the SERVICE.
4. CONSULTANT's liability or any other compensation with respect to the CLIENT and/or third parties is limited to the sum or the sums that will be paid out by CONSULTANT's liability insurance.
5. In the event CONSULTANT's liability insurer does not pay out under the insurance, CONSULTANT's liability for damages or any other compensation with respect to the CLIENT and/ or third parties is in any event limited to the invoice value of the SERVICES that caused damage, with a maximum of EUR 20,000.
6. The exclusions and limitations as referred to in the previous paragraphs of this article will lapse if and in so far as the damage is the consequence of intentional or willful recklessness by CONSULTANT.
7. The CLIENT will indemnify CONSULTANT for any claims by third parties, that are directly or indirectly related to the SERVICES and it will compensate any damages to CONSULTANT that CONSULTANT may suffer as a consequence of such claims.

Article 9 - Default and Termination

1. If the CLIENT does not, timely or properly, comply with its obligations that ensue from the ORDER, CONSULTANT is entitled to suspend the ORDER immediately, without a notice of default or judicial intervention being required, or to terminate it partly or fully by means of a written notification, without CONSULTANT being obliged to compensate any damages, all of this without prejudice to any of its other rights.

2. In the following cases CONSULTANT is immediately entitled to fully or partly terminate the ORDER with the CLIENT by means of a written notification, without a notice of default or judicial intervention; all of this without prejudice to any of its other rights:
 - In case the CLIENT is declared bankrupt, or requests its own bankruptcy or moratorium, or
 - When the CLIENT goes on strike or proceeds to transfer its company or part thereof, including the transfer of the company into a newly to be founded or existing company, or
 - If the CLIENT proceeds to change the purpose of its company.
3. Notwithstanding the provisions above in this article, PARTIES agree that if the PARTIES' opinions differ about the SERVICES rendered by CONSULTANT, or the collaboration between PARTIES in general and PARTIES believe that further collaboration would not lead to the desired outcome as formulated in writing beforehand, both PARTIES shall be entitled to give notice to terminate the ORDER at the end of the month, subject to a one-month notice period. If CLIENT gives notice to terminate the contract subject to the above, it shall nevertheless undertake to refund the costs incurred and yet to incur by CONSULTANT in the context of the terminated.

Article 10 - Applicable Law and Jurisdiction

1. Belgian law shall apply exclusively to these TERMS, as well as to the ORDER. The TERMS and the ORDER express and describe Belgian legal concepts in English and not in their original terms. Consequently all words, terms and expressions used herein are construed and interpreted in accordance with Belgian law.
2. In the event the CLIENT is established in a country that is a participant in the 'Convention on Jurisdiction and Enforcement of Judgements in Civil and Commercial Matters', or in a country that participates in any other enforcement convention with BELGIUM, all disputes that may arise following the ORDER or these TERMS, must be submitted to the competent court in Antwerp, Belgium, subject to the provision that CONSULTANT is entitled to submit claims on the CLIENT to other judicial institutions that are entitled to take cognizance of such claims.
3. In the event the CLIENT is not established in a country that participates in 'Convention on Jurisdiction and Enforcement of Judgements in Civil and Commercial Matters' nor in a country that participates in another enforcement convention with the Netherlands, all disputes that may arise following the ORDER or these Terms and Conditions, must be resolved in accordance with the Rules of Belgium.