GENERAL TERMS AND CONDITIONS OF SERVICE

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1. Scope and acceptance

These terms apply to all quotes, assignments, services and invoices of MEDCOR BV ("MEDCOR"). By accepting a quote or instructing MEDCOR, the client accepts these terms. They prevail over the client's general or purchasing terms. A separate agreement signed by both parties (such as a mandate, quality or technical agreement or framework agreement) prevails over these terms where it deviates from them.

2. Services

MEDCOR provides regulatory affairs, quality assurance, market access, compliance, audit and training services for medicinal products, medical devices, cosmetics, food supplements and related products, including the set-up and audit of ISO management systems. Unless expressly agreed otherwise, MEDCOR's obligations are obligations of means (best efforts), not of result.

3. Statutory and designated roles

Where MEDCOR or its manager acts in a legally designated role, such as Responsible Person (GDP), Qualified Person, Responsible Person for Information and Publicity, PRRC or EU Authorised Representative, the scope and the respective responsibilities are set out in a separate written mandate or agreement. The client provides complete, accurate and timely information, documents and access needed to perform that role. MEDCOR may refuse or postpone a release, approval or sign-off when compliance cannot be confirmed; this does not constitute a breach of contract.

4. Advice and client responsibility

Advice is given on the basis of the legislation, guidance and information available at the time. The client remains responsible for its decisions, their implementation and its products. MEDCOR does not guarantee decisions or timelines of competent authorities or notified bodies.

5. Specialists and subcontracting

MEDCOR may involve qualified specialists from its network for part of the services. They are bound by confidentiality, and MEDCOR remains responsible towards the client for their work. Statutory roles held personally are not delegated without the client's prior consent.

6. Fees and invoicing

Fees are those stated in the quote or agreement and are exclusive of VAT. Hourly services are invoiced on the basis of time spent; fixed role fees are invoiced per month. Travel and third-party costs (such as authority or notified body fees) are charged separately unless included in the quote. Fees may be indexed annually on 1 January in line with the Belgian consumer price index or the wage indexation of Joint Committee No. 200 (PC 200). Invoices are payable within 30 days of the invoice date.

7. Late payment

Any amount unpaid on the due date bears, automatically and without prior notice, late-payment interest at the statutory rate under the Belgian Act of 2 August 2002 on combating late payment in commercial transactions. If a reminder remains unpaid for 8 days, a fixed indemnity of 10% of the outstanding amount (minimum € 50) is also due, without prejudice to the statutory recovery compensation. After written notice, MEDCOR may suspend its services until payment; for statutory roles, the notice terms of the relevant mandate apply.

8. Disputes about invoices and services

Any dispute about an invoice must be notified in writing, with reasons, within 15 days of the invoice date; failing this, the invoice is deemed accepted. Complaints about services must be notified in writing within 30 days of their discovery. A dispute does not suspend payment of the undisputed part.

9. Liability

MEDCOR's total liability, on any ground, is limited to the fees invoiced for the assignment concerned during the 12 months preceding the event giving rise to the claim. MEDCOR is not liable for indirect or consequential damage, including loss of profit, revenue, goodwill or data, product recalls, withdrawals or stock write-offs, and fines or penalties imposed on the client. These limitations do not apply to fraud or wilful misconduct, or where mandatory law provides otherwise. Claims lapse one year after the client became aware of the damage.

10. Confidentiality and data protection

Both parties keep confidential all non-public information received from the other, during the assignment and for 5 years afterwards. This does not apply to information that is publicly available or that must be disclosed by law or to competent authorities or notified bodies; where legally permitted, MEDCOR informs the client beforehand. Personal data are processed in accordance with the GDPR. Where MEDCOR processes personal data on the client's behalf, a data processing agreement is concluded on request.

11. Intellectual property

Deliverables made specifically for the client (such as procedures, files and reports) become the client's property upon full payment. MEDCOR retains all rights to its pre-existing know-how, methods, templates and tools, and may continue to use them.

12. Duration and termination

Unless agreed otherwise, ongoing assignments and statutory roles may be terminated by either party with 3 months' written notice, to allow the timely appointment and notification of a successor. Either party may terminate with immediate effect in case of a serious breach not remedied within 15 days of written notice, or in case of insolvency of the other party. Services performed until termination remain payable.

13. Governing law and jurisdiction

These terms and all agreements with MEDCOR are governed by Belgian law. The parties first seek an amicable solution. Failing this, the courts of Ghent (Belgium) have exclusive jurisdiction. If a clause is invalid, the remaining clauses remain in force and the invalid clause is replaced by a valid one that comes closest to its purpose.